

# Exhibit 3

JIFSAN SYMPOSIUM

ASBESTOS IN TALC

MAIN SESSION

Conducted by Catherine Sheehan

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P R O C E E D I N G S

CATHERINE SHEEHAN: Good morning everybody.

Since we are -- I have 15 minutes to introduce -- welcome everybody. Please bear in mind that we have a webinar aspect of this meeting as well. So in the interest of time, I would like everybody in the meeting room to take their seats, please, so we can commence with the meeting.

So welcome, everybody. My name is Catherine Sheehan, and I've been given the honor of doing the opening and closing remarks. So can I have quiet, please? Thank you.

We do have a webinar component, so we need to keep that in mind as well.

So as part of the introduction, the symposium, as you all may know -- okay. All right. The symposium is organized by the JIFSAN Symposium Committee. Who are the stakeholders supporting this meeting? For those of you that want to know, funding is through a cooperative agreement between JIFSAN and FDA.

The purpose of this symposium is to develop a standard and methodology for analysis and testing of



1 asbestos, and hopefully we'll be able to achieve that  
2 goal here today or at least tackle it in some form or  
3 fashion in that we are providing a forum for experts.  
4 We have an audience from regulators, industry, and  
5 academia, so I think we are well-equipped here to  
6 hopefully move this discussion along.

7 I see some folks in the audience as well that  
8 I know of to work with the United States Pharmacopeia.  
9 So we also -- if you don't know, the United States  
10 Pharmacopeia also have a standard for talc; and we,  
11 also, are very interested in the work that is going on  
12 today. Of course, we will share knowledge and come to  
13 a consensus on future testing approaches and adequately  
14 analyzing talc containing products for the presence of  
15 asbestos fibers; and this symposium will include  
16 presentations and, most importantly, the concurrent  
17 breakout sessions on test methods, characterization,  
18 and interpretation of data.

19 So that's kind of a lineup in terms of what  
20 our purpose and goals are. Let me see if I can get  
21 this thing moving.

22 Tim, help. It's not moving. Technical

1 difficulties here. It doesn't seem to want to move.

2 All right.

3 So morning session -- briefly, we have divided  
4 the morning session into three key areas: definitions  
5 and mineral fibers, test methods, and a break, and then  
6 followed by two sessions of presentations on the  
7 interpretation of data obtained from microscopy  
8 measurements.

9 The afternoon session, the breakout sessions,  
10 you can see here we have -- Sessions A, B, and C will  
11 be repeated to allow each attendee to have a chance to  
12 participate in two of the three planned sessions.

13 Session A, test methods for analysis of talc  
14 and mineral fibers in cosmetics; and Session B,  
15 measurement criteria for identification and fiber  
16 counting; and then Session 3 will be the interpretation  
17 of the testing data.

18 So after that -- some important information  
19 here in terms of housekeeping and how we're going to  
20 handle the breakout. Co-moderators will pose questions  
21 and record input from the audience using flip charts,  
22 computers, and other audio/visual aids. In addition to

1 that, notetakers are available among participants, and  
2 they may use recording devices. Also, transcriptionist  
3 will be on site. And then immediately after the  
4 breakout session, there will be a break during which  
5 the co-moderators will review the input from the  
6 audience and draft their summary to report out to the  
7 larger group.

8 So after the break -- after the breakout  
9 sessions, all attendees will reconvene for the record  
10 out session; and then each pair of the session co-  
11 moderators will give time to deliver an oral summary of  
12 the input to attendees.

13 During the symposium, most importantly, there  
14 will be time for Q&As and if all questions are not  
15 answered, they will be posted on the JIFSAN website,  
16 and a summary of the meeting will be available shortly  
17 after the meeting. And so the date that I have here is  
18 that the moderator/speaker will present the summary of  
19 the presentation or results by January 5th. So you  
20 won't get anything before that date.

21 So any questions on that? One more thing, the  
22 restrooms are directly behind the registration desk.

1 That's it. So --

2 AUDIENCE MEMBER 1: Where will the breakout  
3 sessions go? Where are the breakout sessions?

4 CATHERINE SHEEHAN: Good question, Marty  
5 . Very good question.

6 Help, JIFSAN.

7 TIM: They are two corridors down behind us.  
8 So if you got out of the elevators, you just go  
9 straight.

10 CATHERINE SHEEHAN: Okay. I'm sure we will  
11 get more information. I'll go and find out and get  
12 everybody familiar with the three certain breakouts.  
13 Okay.

14 AUDIENCE MEMBER 2: Catherine?

15 CATHERINE SHEEHAN: Yes.

16 AUDIENCE MEMBER 2: Could you explain a little  
17 bit about the webinar and what it is and where it's  
18 going and --

19 CATHERINE SHEEHAN: Good question as well.  
20 The webinar has just been communicated to me by Tim.  
21 So my understanding is that we have this webinar going  
22 on, and we are recording this as well.

1 Tim can -- I think that's all we know about  
2 now in terms of they're listening to our presentations.

3 AUDIENCE MEMBER 2: Who is they?

4 CATHERINE SHEEHAN: Anybody that was invited  
5 to this JIFSAN meeting that cannot attend in person --

6 AUDIENCE MEMBER 2: Okay.

7 CATHERINE SHEEHAN: -- has the ability to  
8 join by webinar, so --

9 TIM: I do believe there's only like five or  
10 six people.

11 CATHERINE SHEEHAN: Okay. Thank you, Tim.

12 All right. So with that, we'll move on.

13 AUDIENCE MEMBER 2: Is there Wi-Fi access in  
14 this room?

15 TIM: Yes. I can come around and talk to you.

16 CATHERINE SHEEHAN: Okay.

17 AUDIENCE MEMBER 3: Just for technical  
18 difficulties, I had -- I'm getting a message from  
19 somebody that's on the webinar, but they can't hear  
20 anything. They can see the screen, but they're unable  
21 to do that. I don't know. Is there a way for them to  
22 contact help for that?

1 CATHERINE SHEEHAN: I see.

2 TIM: I am -- I'm actually listening to the  
3 webinar, and it's being broadcast just fine.

4 AUDIENCE MEMBER 3: Okay.

5 TIM: So --

6 AUDIENCE MEMBER 3: Do you have, like, an e-  
7 mail or something that I can have him reach out to you  
8 to --

9 TIM: Yes.

10 AUDIENCE MEMBER 3: -- get help?

11 CATHERINE SHEEHAN: Yeah, that would be good.  
12 Yeah.

13 TIM: Just Tshaffer@dodwu.

14 Who needed the Wi-Fi?

15 CATHERINE SHEEHAN: Right. Yeah. If they had  
16 an e-mail just in case they have any questions. Okay.

17 So in the interest of time, let's move on, and  
18 then I'll navigate through this.

19 TIM: Okay.

20 CATHERINE SHEEHAN: Okay. So our first  
21 speaker this morning -- very briefly introduce Brad Van  
22 Gosen. He's a research geologist at the U.S.

1 Geological Survey, and he began his work with asbestos  
2 in 2000, so if Brad could come up to the podium.

3 BRADLEY VAN GOSSEN: First of all, I want to  
4 thank the JIFSAN committee for the opportunity and the  
5 invitation to speak here today. It's very much  
6 appreciated.

7 I'm hoping that my product will just provide a  
8 context for the rest of the day, and that is to just  
9 describe to you the elongate mineral fibers, particles  
10 that we're even going to need to think about in terms  
11 of commercial talc deposits. And I'm going to do this  
12 and -- these minerals will be some of the amphibole  
13 mineral group as well as the one type of deposit that's  
14 relatively spatially associated with Chrysotile, the  
15 serpentine mineral group.

16 The amphiboles and serpentine that are  
17 associated with talc deposits of mineable commercial  
18 size are dependent entirely on the geologic  
19 environment, the geologic conditions that form that  
20 type of deposit. I'll describe four basic types of  
21 geologic settings and conditions that form talc  
22 deposits -- not all are created the same -- and give



1 you a little geology.

2 I thought I'd provide just a quick background  
3 on the current talc production. In the United States  
4 there are three companies producing from three  
5 different states, and these include the American Talc  
6 Company, which operates several pits in the Allamore  
7 District, which is in far western Texas. Most of their  
8 product is being used in paints is my understanding.  
9 Barretts Minerals operates two large open pit mines in  
10 southwestern Montana, and then Imerys operates the  
11 Yellowstone Mine also in southwest Montana and another  
12 mine here in Ludlow, Vermont.

13 The photo there is a distant view of the Yellow  
14 stone Mine, which is the largest talc producer in the  
15 U.S. for several years now. By state, production is  
16 largest from the Montana deposits followed by Texas and  
17 then Vermont.

18 Just a little background on our most recent  
19 domestic talc production and uses. This is information  
20 from our USGS National Minerals Information Center. In  
21 2017, the last data that's been published, U.S.  
22 production was estimated about 540,000 metric tons,



1     valuated at about 108 million dollars. And at least  
2     during 2017, the talc that we [the U.S.] produced and  
3     sold was used mainly, as you can see, in ceramics,  
4     paint, paper; followed by plastics, rubber,  
5     refractories, roofing; and just about 3 percent was used  
6     in cosmetics.

7             We [the U.S.] export about 210,000 metric tons  
8     per year. We also import an estimated 380,000 metric  
9     tons of talc, as compared to 540,000 metric tons that we  
10    produce commercially. So talc is actually one of the  
11    rare mineral commodities in the U.S. these days that we  
12    produced more than we import, but it's still a  
13    considerable amount of import. By decreasing the amount  
14    by tonnage, about three-fourths of our imported talc was  
15    used in cosmetics, paint and plastics. So if you  
16    include imported talc and domestic production, the  
17    primary uses are plastics, ceramics, paint, paper,  
18    roofing, rubber; and cosmetics is a distant end of the  
19    spectrum.

20            According to our Minerals Information Center,  
21    the main import sources in recent years have been  
22    Pakistan (35%), Canada (28%), and China (26%), and a  
   small amount of processed talc coming from Japan (5%).

1           Just the very basics to get you started. Talc  
2   is a magnesium silicate mineral. As you've heard, it's  
3   probably -- it's number one on the Mohs hardness scale,  
4   meaning, it's used as the example of the soft mineral.  
5   It has perfect cleavage on the 001 plane, basically  
6   meaning that it's very platy, usually; but as we will  
7   see, and as you know, there are fibrous varieties of  
8   talc.

9           There are very weak lines between the layers,  
10   so they're easily sliding past each other. It gives  
11   talc its greasy and slippery feel and its very low  
12   hardness. Well-developed, sort of, gem-quality  
13   crystals of talc are extremely rare; and common  
14   impurities include nickel, iron, aluminum, calcium,  
15   sodium, and some excess water, iron probably being the  
16   most common impurity to ideal composition of talc.

17           This is the amphibole group of the regulated  
18   amphibole minerals we all know and love, if they occur  
19   and when they occur in the asbestiform habit, which  
20   will be discussed much today. Of these, principally,  
21   the minerals -- amphiboles that we're going to find in  
22   the commercial scales talc deposits are anthophyllite,

1 actinolite, and tremolite. There is and, of course,  
2 has to be always an exception in geology. There is  
3 some manganese variety of cummingtonite in the New York  
4 deposits that's also been reported and well documented,  
5 but for the most part, we're gonna -- I'll show you  
6 examples of different deposit types, and we're gonna  
7 find that anthophyllite is very common. Tremolite's  
8 very common, and occasionally, as part of the  
9 actinolite/tremolite series, we'll find some  
10 actinolites in deposits.

11 We also -- as I said, spatially, in one  
12 deposit type I'll show you. Chrysotile is associated  
13 in the -- abounding in wall rock, country rock; and  
14 chrysotile, being of the amphibole -- or I mean -- I'm  
15 sorry -- of the serpentine mineral group. But if  
16 you'll notice the formula for anthophyllite, chrysotile  
17 and, if I back up to the other amphiboles, magnesium,  
18 silica, and water hydroxyls are the critical elements  
19 to form all of these -- the regulated asbestos  
20 minerals. And also, if you notice, talc is, again, a  
21 magnesium silica hydroxyl formula. So the same  
22 chemistry involved in the formation of the amphiboles

1 is also the same chemistry in the -- or critical  
2 elements that form talc, so it's not unusual to find  
3 the amphiboles in a talc deposit, at least based on the  
4 chemical components of the systems.

5 Talc is a replacement mineral. For example,  
6 it doesn't form, you know, straight from a magma like  
7 mag minerals. It's replacing a preexisting magnesium-  
8 rich mineral with preexisting magnesium-rich host rock,  
9 and these would include either a dolostone -- you've  
10 heard of dolomite, a magnesium calcium carbonate rock -  
11 - or replacing an ultramafic rock, which is a magnesium  
12 iron-rich metamorphic rock. So you have the magnesium  
13 in the host rock already available, and then, if  
14 heated, core fluids, usually waters, carrying silica in  
15 solution, react with the host rock to provide the  
16 elements to form talc. And these processes can be  
17 driven by regional metamorphism, tectonic scale, and a  
18 regional scale, heat and pressure, whereby, contact  
19 metamorphism where igneous intrusion of magma intruded  
20 directly into the host rock or the -- by the  
21 circulation of magnetic hydrothermal fluids. Those are  
22 heated fluids, heated by magma that's at depth that

1 didn't come in direct contact with the host rock, but  
2 I'll show you examples in the United States of each of  
3 these.

4           Probably our best example of regional  
5 metamorphism in this case is -- cold stone magnesium  
6 calcium carbonate is a good -- our best example of a  
7 regional metamorphic talc deposit. These were mined on  
8 really for the first time on a larger scale mainly  
9 underground mining, but a lot made smaller open pits  
10 starting in 1948, shown by the red squares; and then  
11 the open pit -- larger open pit operations were from  
12 1974 till about 2008 when the mines closed, shown by  
13 the hot pink ovals.

14           The conditions that form these deposits over a  
15 billion years ago, again, were from regional  
16 metamorphism shortening the depression of the crust in  
17 that region over a large area; and this drove the  
18 fluids, under high heat and pressure, from the silica  
19 being gathered from silica-rich rocks beneath and then  
20 probably accessing fault and fracture systems, moving  
21 the silica in fluids up into the dolomite, massively  
22 replacing portions of the dolomite by talc and



1 amphiboles.

2           This is -- take you back to chemistry a little  
3 bit, but these were -- progressive reactions from top  
4 to bottom go from highest heat and pressure down to the  
5 lower portions of heat and pressure in the system as  
6 the system start to relax and heat also decreased.

7           First we take dolomite in the presence of the  
8 invasion of that silica in fluids to form tremolite and  
9 calcite. Carbon dioxide can easily leave the system.  
10 Now we have tremolite in the presence of the remaining  
11 dolomite, again, with waters involved can form  
12 anthophyllite and calcite; and as the heat and pressure  
13 decreased even further, that new anthophyllite in the  
14 presence of siliceous waters, again, forms talc. This  
15 is a progressive stepwise occurrence that are in this  
16 metamorphic system, starting with a dolomite -- a  
17 magnesium calcium source rock.

18           Most of the tremolite in these deposits is  
19 described as, I would say, prismatic in shape. They're  
20 elongate but certainly not clearly fibers. But then  
21 you have this fibrous talc, which is the replacement of  
22 the anthophyllite, formed during phase 2, if you will;

1 and the talc has, occasionally, partially to completely  
2 replaced the fibrous anthophyllite; and this gives the  
3 -- the terms fibrous talc or tremolitic talc have been  
4 used to describe the Gouverneur talcs, and this shows  
5 you a map of why.

6 And then we also have quite a few of these  
7 transitional fibers, which are the partial and  
8 sometimes complete replacement of the preexisting  
9 anthophyllite by talc, so it can get very complex.

10 Our next deposit type to consider are these  
11 amphibole. They're tremolite. They're in talc  
12 deposits in the southern Death Valley region. I  
13 started studying these about 15 to 16 years ago, just  
14 curious to see what the morphology of the tremolite  
15 within these deposits looked like under high  
16 magnification. They're -- well, I should go back a  
17 little.

18 There are 43 talc deposits that were either  
19 mined or prospected in the Death Valley region,  
20 including a couple dozen within Death Valley National  
21 Park itself. These became part of Death Valley  
22 National Park. They are now property of the national

1 park when the national monument was converted to  
2 national park status in 1988. There's still a couple  
3 dozen other talc deposits outside of the realm of the  
4 national park boundaries which lie on a mixture of  
5 mined claims and federal lands. These talcs were used  
6 primarily in ceramics, especially ceramic tiles, as an  
7 -- and as an extender within paints. This is an  
8 example of some of the mines outside of the national  
9 park. As I said, there's quite a few. They're easy to  
10 spot from long distance. White piles against the gray  
11 dark background of the region. I'm getting hot looking  
12 at this again. (Audience laughs.) It was 110 that day.  
13 There are a combination of open pits and underground  
14 mines that are actually not deep underground mines.  
15 They're just added straight into the talc tremolite ore  
16 bodies.

17 This is a schematic diagram from Warren  
18 Wright's very fine descriptive report on the Death  
19 Valley deposits. He has a description of each one of  
20 those 43 deposits in the region. It's more of a  
21 general geology discussion. He did not have the use of  
22 microbeam technology to look at very fine fibers at



1 that time, but it's a very good guide to where these  
2 occur in their basic geology.

3 And, essentially, what you have is that gabbro  
4 soil is the magma that intruded into the tridy (ph)  
5 dolomite, which is a term being silica; and it's a  
6 silica magnesium carbonate-rich host rock providing the  
7 magnesium for this reaction; and this reaction formed a  
8 talc-tremolite orebodies which can be generally around  
9 50 feet in thickness. So the heat drove this reaction.  
10 Warren has suggested, and it seems reasonable, these  
11 sediments may have actually been -- or this dolomite  
12 might have actually been a sediment -- part of a  
13 sediment sitting on the shallow ocean floor when it was  
14 intruded by the magna; and this could accomplish some  
15 of the sodium we find in a little bit of the mineralogy  
16 in here. So in the end, this reaction formed talc -- a  
17 mixture of talc, tremolite, calcite, dolomite, and  
18 quartz. So these were not considered, therefore, a  
19 high-purity talc; but they are very suitable for use in  
20 ceramics and paint.

21 This is just a good view of the system I just  
22 showed schematically. The gabbro soil magma that

1 intruded into the tridy dolomite -- the silk magnesium-  
2 rich host rock -- and the reactions on the talc  
3 tremolite rock would be the ore itself; and it has very  
4 sharp contact between the intrusion and the talc  
5 tremolite rock, the replacement of the dolomite. You  
6 put your finger on that. And forgive me, I'm a  
7 geologist, I got to show some of these details; but  
8 they're very layered sometimes, and it's very crumbly.  
9 The advantage of mining talc is that it generally  
10 doesn't require blasting. Heavy equipment can easily -  
11 - you're talking about the softest rock, and if you  
12 find a talc rock that's even the least bit hard, that  
13 means it has a fair amount of quartz or calcite in it.  
14 There's a little rock number for -- scale number on the  
15 side there.

16 So what we see, via scanning electron  
17 microscope, is a wide variety of shapes and  
18 morphologies within the tremolite in the Death Valley  
19 talc. For the most part, what I describe as  
20 "prismatic" is the most common form; but we do find  
21 these circular needle-like particles of tremolite and  
22 some that are very characteristic of the stuff it

1     formed. For example, we find fiber bundles of  
2     tremolite mixed with the clay you tab (ph), or if the  
3     analysis was by electron dispersive spectrometer that  
4     is, of course, part of our SEM, so -- and we do find  
5     these -- most of these are dust, dabbed from the inside  
6     of the plastic sample bag; so these would represent  
7     dust that easily release here in the sample, but we did  
8     find plenty of individual fibers in the dust and little  
9     -- again, fiber bundles. The Smith liner is east of  
10    the park, and I've been told that there is a company  
11    that in recent years has been looking -- or has been  
12    excavating former stockpiles of talc, and I'm not sure  
13    it's being shipped to a paid factory or not, but this  
14    is something I think should be kept in mind.

15           We also found scattered particles with a sodic  
16    composition. Again, this is from electron dispersive  
17    spectroscopy, which would not be considered a precise  
18    method; but they're clearly a sodic-calcium amphibole,  
19    and the best fit would -- from our work is the  
20    amphibole winchite. And, again, we find some fibers  
21    and fibrous bundles that fit another sodic-calcic  
22    amphibole being richterite.

1           So my point here is these Death Valley talc  
2       deposits formed by contact metamorphism where the magma  
3       protruded directly into the host rock I think need to  
4       be considered if you -- oh, we hear of activity of re-  
5       mining these deposits and the dust that can be created.

6           Our third category of talc-forming  
7       environments include the replacement of ultramafic  
8       rocks. These are magnesium iron-rich rocks formed by  
9       either metamorphism and alteration of an olivine-rich  
10      rock, a pyroxene-rich rock or an amphibole-rich rock;  
11      and these alter to form a rock called serpentinite,  
12      which is a serpentine-rich mineral -- or serpentine-  
13      rich rock; and these can, of course, as we know on many  
14      instances, contain chrysotile and occasionally and  
15      sometimes anthophyllite and tremolite.

16           This is a very cartoonish diagram of work by  
17      Rick Sanford in 1982, his long article in the  
18      American Journal of Science, which is basically a  
19      summary of his Harvard PhD study. And first of all, he  
20      determined, at the bottom there, these reactions  
21      occurred at very high temperatures, very high  
22      pressures; and this would be -- it's hard to generalize

1 a complex system, but this would be the general  
2 zonation of what would be visible at the Vermont talc  
3 deposits, for instance. And on the left, they're  
4 replacing an ultramafic rock, that magnesium-rich,  
5 serpentine-rich; and those can, certainly locally,  
6 contain chrysotile, tremolite, actinolite, and  
7 anthophyllite.

8 You move inward towards the talc ore, you have  
9 a talc carbonate rock, a talc with magnesite --  
10 magnesium carbonate unit, which contain lesser amounts  
11 of dolomite and calcite, and evidence of talc replacing  
12 apophyllite. And we move into the talc zone, which it  
13 is often described as a high-purity talc, meaning it  
14 really has a little courser clay or calcite. It's not  
15 gritty. It's a very soft, relatively pure talc.

16 The occurrence of anthophyllite mentioned or  
17 actinolite or tremolite fibers within this talc were  
18 still a matter of some debate. I, personally,  
19 unfortunately, have not been able to look at any of the  
20 raw ore, but I welcome samples or an opportunity to  
21 sample.

22 This is bounded by an actinolite fluoride-rich

1 rock. There's evidence of talc replacing actinolite to  
2 minor amounts. Perhaps much of this is actually  
3 tremolite. Rick did not have the benefit of microbeam  
4 analysis at the time.

5 Then we move outward to the altered country  
6 rock, which is the country rock being a metamorphic  
7 silica-rich rock or gneiss; and some of the metamorphic  
8 texture remains, and you have some prismatic classic  
9 amphiboles and then outward to the unaltered gneiss on  
10 the opposite side of the system. So you're getting  
11 this silica sourced by the country rock and the  
12 magnesium clearly sourced by the ultramafic rock, and  
13 it's a complex system that occurred under very high  
14 heat and pressure.

15 But the good news, not all talc is created  
16 equal. There are another type of talc deposit. These  
17 are formed like the upward circulation of hot silica-  
18 rich fluids that are heated by igneous intrusion that  
19 lies at depth. It's not coming in direct contact with  
20 the host rock, and these can form very large talc  
21 deposits by the massive replacement of that dolostone  
22 and magnesium-rich marble; and in this system no

1     amphiboles or serpentine are created. And they're  
2     relatively simple reaction on a stone, like, again,  
3     heated silica -- or heated fluids would carry silica,  
4     forming talc calcite and carbon dioxide.

5             This is a very cartoonish depiction of that,  
6     but you have the magma rising through the crust heating  
7     any fluids, core fluids or even if groundwaters exist  
8     in the system. The black lines representing fault and  
9     fracture systems which surely help to plum the heated  
10    waters upward through silica-rich metamorphic sedentary  
11    rocks that can provide the silica and then massively  
12    replacing parts of the magnesium-rich marble above.  
13    The edges of the deposit can have considerable quarts,  
14    calcite, and dolomite, and pockets within the talc  
15    body; but for much of the talc body, more than 90  
16    percent of it is platy talc. There's a -- of --  
17    deposits of this type in a quarter -- we're in  
18    southwestern Montana -- are very large deposits, and  
19    these may be -- this may -- probably represents the  
20    largest talc district mill in the United States; and  
21    they all form from the replacement of those dolomitic  
22    marbles, intrusions at depth; and this includes the



1 Treasure Mines and the Regal Mines of Barrett Minerals  
2 and the Yellowstone Mine of Imerys.

3 This slide and the next I credit to Childs  
4 Geoscience, consulted out of Bozeman, who published one  
5 of his PowerPoint presentations. This is a generalized  
6 geologic map of the Yellowstone Mine area, the  
7 Yellowstone deposit. The blue being the marbles that  
8 have been replaced. The red is the talc -- the talc or  
9 body which is about a half a mile in length north and  
10 south, and all the black lines being fault systems  
11 which surely helped plumb the -- in the plumbing system  
12 for the heated silica-rich fluids that moved up and  
13 invaded and replaced the dolomite.

14 That Burlington northern pit up at the north  
15 was another large talc deposit mined many years ago,  
16 and that pit has been reclaimed.

17 The Yellowstone talc mine itself, it's very  
18 large. It's the largest known talc deposit in the  
19 United States. I'm not here -- I want to make it  
20 clear, I'm not here to endorse the deposits of  
21 southwest Montana. I'm just making the point that not  
22 all talc deposits are created equal. Some can lack



1     amphiboles we plan to discuss, but it -- my work has  
2     led me to show that the geologic conditions that came  
3     to form the talc deposit directly impact whether  
4     amphiboles or serpentine, in one case, exist at all to  
5     discuss.

6             And as a lead into Greg's talk, again, I want  
7     to emphasize that even within one talc district, or even  
8     within one talc deposit, you can get a wide range of  
9     mineral morphologies; and these may not be obvious or  
10    visible without microbeam analysis. So I think we need  
11    to -- well, this will be discussed all day long  
12    hereafter; but there will -- to get down to the scales  
13    that clearly show this variation, it may require things  
14    beyond standard microscope work.

15            And with that, thank you for your time; and  
16    hope we can -- well, you'll hear a lot more in  
17    discussion today about -- that led to the  
18    identification of this type of variation. Thank you.

19            (Applause)

20            CATHERINE SHEEHAN: Thank you, Brad.

21            I think we can move along and get Greg up, and  
22    then we have time for Q&A.

1           So introducing Greg, he's a research scientist  
2 specializing in the characterization of fibers and  
3 asbestiform minerals. Greg worked as a mineralogist  
4 and geologist in the U.S. Geological Survey for 23  
5 years before his retirement from federal service; and  
6 in 2009, Greg served as a member of the National  
7 Academy of Science Institute of Medicine Committee to  
8 review the NIOSH program for asbestos research.

9           Greg, thank you.

10           GREGORY MEEKER: Good morning. Catherine,  
11 thank you for the introduction.

12           I'd like to thank JIFSAN for inviting me here  
13 today to give this talk. It's good to be back in the  
14 mix. I've been retired now for six years and enjoying  
15 it, but it's good to see a lot of my old friends here.

16           I want to put up this -- oh, and Nora --I want  
17 to thank Nora so much for all the hard work she's done.  
18 She's really put this together, and thank you very much.  
19 I never see her in the room.

20           I guess I need to put up this disclosure here.  
21 I have done a little bit of consulting since I retired  
22 from USGS, but mostly I've been enjoying summers in

1 Colorado and winters in Florida.

2 So the question today is: Has anything really  
3 changed in the last 15 years? And I chose 15 years  
4 because I'm going to use a presentation that was put  
5 out 15 years ago, and I think we're still having some  
6 of the same arguments today that we were then.

7 This is going back a little farther to 1981.  
8 Well-known and important mineralogists from University  
9 of Minnesota, and he wrote a paper, and he wanted to --  
10 said, "Asbestos is one of the most durable [sic]  
11 industrial minerals because it possesses an unusual  
12 combination of exploitable properties, such as long  
13 fibrous shape, high tensile strength, and flexibility,  
14 both thermo and electric conductivity, high absorbency,  
15 high chemical and mechanical durability and  
16 incombustibility." And then he says, "Ironically,  
17 industrial desirable properties of asbestos also appear  
18 to be responsible for carcinogenicity."

19 I'm gonna come back to this at the end of the  
20 talk, but I just wanted to put that out at the  
21 beginning because it -- I think it kind of frames the  
22 whole discussion.

1           So I think the questions for us here today --  
2       it was hard for me to know quite what to talk about,  
3       but I -- is it possible to protect human health without  
4       regulating everything? Is regulated asbestos the only  
5       health hazard? Is commercial-grade asbestos the only  
6       health hazard? Not necessarily the same thing. And  
7       what have we learned over the last 15 years about  
8       asbestiform and related minerals? Most important  
9       question is: What does the human lung or the human  
10      body know about all of this?

11           Now, traditional analytical methods may not be  
12      adequate for characterizing natural-occurring asbestos  
13      or contaminated materials. Most of the methods we use  
14      today were developed for the analysis of commercial  
15      asbestos. It's when you've got asbestos in ceiling  
16      tiles and floor tiles or asbestos in the siding and you  
17      want to go in and find out if that material is still  
18      there after a clearance or if workers are being exposed  
19      in production. So you're dealing with a known --  
20      you're dealing with a commercial-grade material, and  
21      the methods -- most of them -- were developed to look  
22      at that -- the EPA 600, an analysis of asbestos in

1 building materials.

2           There are very -- there's so much nomenclature  
3 and definition -- issues with definitions to talk about  
4 that we could have a meeting like this for two weeks  
5 and just begin to get into the issues, so it's -- one  
6 of the issues is the name of an amphibole and how well  
7 can we identify an amphibole. Some are listed in the  
8 ranks, others are not. Actinolite and tremolite are  
9 listed in the government regulations;  
10 magnesiohornblende is not; richterite is not; winchite  
11 is not; and the analytical methods we have to identify  
12 these different amphiboles, because they're based on  
13 chemistry, is -- it's not easy to do.

14           And this is an electron probe microanalysis of  
15 a -- probably an actinolite particle, and it was done  
16 in an electron microprobe on a bulk sample -- polished  
17 bulk sample. It's probably the most accurate chemical  
18 analysis you can get on a micron or two micron spot,  
19 and according to Leake, if you look at this --

20           MAN: I can't see it.

21           GREGORY MEEKER: -- the pointer -- if you look  
22 at the diamond right here, if you use the method in



1     Leake 97 to identify what this mineral is, you get that  
2     point right on the line between actinolite and  
3     magnesium -- magnesiohornblende. If you change the way  
4     you calculate the analysis, if, for instance, you use  
5     all ferric iron, or all ferrous iron, to make the  
6     calculation, because an instrument cannot tell the  
7     difference, you could end up with a point up here or a  
8     point down here and other ways of calculating the  
9     analysis will fall in between these two lines.

10           So the point is that even the best analysis  
11     you can get on a very tiny spot does not -- you've got  
12     air barns (ph) here. You don't really know if you're  
13     looking at actinolite or magnesium --  
14     magnesiohornblende.

15           I'm not gonna talk anymore about chemistry  
16     because I think the issue here today is morphology, and  
17     that's because the amphiboles that you find in talc are  
18     fairly easy to identify chemically on a TEM with  
19     crystal structure. So the chemistry is not as big an  
20     issue with the -- usually with the minerals you find in  
21     talc, except for the -- the few that Brad talked about  
22     -- the richterites and winchites.

1           So let's talk about morphology. Traditional  
2     thinking, I think, uses an in-member (ph) approach.  
3     In-member is a term that enterologists are familiar  
4     with. It's an in-member approach with no solid  
5     solution, which means you either have one solution at  
6     one end and the other and nothing in between. I think  
7     this is a way to look at it is stove piping. So you  
8     either have commercial-grade asbestos over here or you  
9     have everything else, which really, over the last about  
10    30 years, have incorrectly been termed "cleavage  
11    fragments." Some of them are; some of them are not;  
12    but it's just all been kind of dumped into this one bin  
13    that everyone seems to call cleavage fragments. So  
14    it's either the bad stuff -- whoops. Sorry. It's  
15    either the bad stuff over here on the right or the  
16    stuff that doesn't hurt you on the left.

17           Well, there are a lot of definitions for  
18    cleavage fragments; and I mean, I can't read all of  
19    this, but they're really all saying the same thing.  
20    And the summary, I think, is that cleavage fragment is  
21    not any particle that does not meet some specific  
22    definition of asbestos, and there are a lot of

1 definitions of asbestos also. Cleavage particles must  
2 be particles broken from larger crystal, along specific  
3 crystallographic point. So it's not only a broken  
4 particle, it's broken in a certain way related to the  
5 crystal structure in the mineral.

6 EMP. Why people don't like the term "EMP."  
7 EMP is a general term for any elongate mineral  
8 particle. It could be a cleavage particle. It could  
9 be an acicular crystal. It could be an asbestiform  
10 particle. The term was meant to be used for research,  
11 not for regulation.

12 Cleavage fragments, over the years, in my  
13 opinion, have become the proverbial get-out-of-jail-  
14 free card; and that's due to misuse and  
15 misunderstanding of the terms: asbestos, asbestiform,  
16 cleavage fragment, and a whole bunch of others. The  
17 term "EMP" is not meant to be used in place of specific  
18 mineralogical nomenclature when the correct terms are  
19 known and when they are properly used. A lot of these  
20 terms are misused, and that's a problem.

21 I want to go into this presentation. I think  
22 at least one of the primary authors is here, Ann Wylie.



1 I don't know if Kelly Bailey is here, but I want to use  
2 this. There's a lot of good information in here. I  
3 want to say that at the beginning, and there's a lot of  
4 good health information that I'm not going to get into;  
5 and we need another meeting like this to deal with  
6 that, but I want to use this to illustrate some of the  
7 points that I feel important.

8 The introduction says, "Despite this  
9 attention, a clear understanding of what asbestos  
10 actually is remains a source of confusion to many," and  
11 that's very true; but that's also talking about  
12 commercial-grade asbestos. "No federal regulatory  
13 agency treats elongated nonasbestiform particles as  
14 asbestos, yet some in the regulatory and health  
15 community believe they should. These individuals  
16 mistakenly believe that the essential differences  
17 between nonasbestiform minerals and asbestos is not  
18 significant," and that's getting back to the first  
19 slide I showed from Zoltai from 1981. And I think a  
20 lot of people here would agree with this, and I think  
21 there are a lot of people who would not.

22 "Health researchers who fail to understand

1 these differences can assign and have attributed the  
2 carcinogist -- carcinogenic" -- excuse me -- "effects  
3 of asbestos exposure to nonasbestiform minerals."

4 And so here is an example from that  
5 presentation showing what asbestos should look like,  
6 and again, I think this is a good example of good  
7 quality commercial-grade asbestos, particularly  
8 serpentine; but it says the single most important  
9 morphological characteristic of the asbestiform habit  
10 is the fibrous polyfilamentous characteristic.

11 This is an example that I think shows what  
12 that drawing -- previous drawing was trying to show.  
13 You can see these features -- very thin fibers,  
14 parallels, maybe some curvature there. This is  
15 tremolite from Death Valley. I think Brad had this  
16 image or took this image. It's from the USGS website -  
17 - on the microprobe website.

18 This is the diagram showing the nonasbestiform  
19 particles, and nonasbestiform crystal growth tend not  
20 to grow -- excuse me -- not to grow with parallel  
21 alignment. They form multidirectional growth patterns  
22 instead. I guess they're saying that crystals are

1 strong, but crystals grow in a cluster like that. And  
2 then it says that when pressure is applied, they easily  
3 break apart and form the particles that you see over on  
4 the right with stair-steps on the surface and -- so if  
5 we tried to find one that looked like this, maybe this  
6 one would be a good example. This is an amphibole  
7 particle. The -- let me get this pointer. You can see  
8 these stair-step patterns on the edge. Maybe if we  
9 look a little closer, I think this looks very much like  
10 this guy over on the right here; but you've got these  
11 steps on the side, kind of a flat top. Things look  
12 like they might be breaking off or partially broken off  
13 on the side.

14 So what is this that we're looking at? This  
15 is UICC crocidolite, and you know what? Ore mag looks  
16 like this. There are a lot of particles that look like  
17 this, and maybe some people would call those cleavage  
18 fragments, and then here's the particle we looked at  
19 earlier.

20 Another publication that came out in '77 from  
21 the Bureau of Mines. This one's showing massive  
22 anthophyllite here and massive actinolite over here and

1 then saying that this is not asbestos. Anthophyllite  
2 asbestos looks like this. Actinolite asbestos looks  
3 like this.

4 I'd like to show you some other images of a  
5 similar theme. Here's a massive gem part richterite.  
6 This sample is very hard. If you hit it with a hammer,  
7 it will crack. You can't just peel it apart like we  
8 used to do in mineralogy class decades ago. And then if  
9 you look at -- down here there's some little particles,  
10 and if you look at those particles, if you can just kind  
11 of brush off the surface, that's what they'd look like.

12 Here's another one. El Dorado Hills tremolite.  
13 Again, it's a massive-looking rock here. Hit it with a  
14 hammer, it's hard, it will crack; but it sheds  
15 particles, and this is what those particles look like  
16 under the SEM.

17 Here's Libby. This is a very hard rock. I  
18 spent a lot of time beating on these rocks. (Audience  
19 laughs.) And believe me, they are hard, and -- but this  
20 stuff just flakes off the surface. If you look at it  
21 under the microscope, that's what you get. This is  
22

1 from USGS publication on El Dorado Hills from 2006.  
2 And this curve on the left is from camera 77 showing  
3 the aspect ratio versus frequency for particles that  
4 they classified as cleavage fragments, and you can see  
5 they're all down here with a very low aspect ratio.

6 They also did asbestos particles. I can't  
7 remember what they used, but this curve for asbestos is  
8 hard to see; and I apologize, but if you follow the  
9 pointer, it goes way out here, and the aspect ratios  
10 can be very high.

11 Well, the material from El Dorado Hills,  
12 California, falls in between. It's not here, and it's  
13 not under this -- similar to this asbestos curve. It's  
14 in between. These are not from a single deposit.  
15 These are particles that were gathered over a wide area  
16 that come from a range of sources, but still, they're  
17 in the dust that people are breathing in the park in El  
18 Dorado Hills.

19 This is Libby showing kind of the same thing.  
20 There's asbestiform material. There's stuff pretty  
21 much everybody would call cleavage fragments, a lot of  
22 stuff in between. Here's the asbestiform cleavage

1 fragments, but I've looked at a lot of this material,  
2 and most of it looks like this. What do you call that?

3 Again, here's another Libby particle. It's  
4 got a little bit of everything. There's very long,  
5 very thin things breaking off up here. There are  
6 things breaking off that look like cleavage fragments.  
7 Top of the slab, you've got structures like you see  
8 here. What do you say about this? I say it's very  
9 difficult to say what this is, but I think a lot of  
10 people here would agree that there are hazardous  
11 particles here.

12 AUDIENCE MEMBER 4: It's not respirable.

13 GREGORY MEEKER: Pardon me?

14 AUDIENCE MEMBER 4: The particle you showed is  
15 not respirable.

16 GREGORY MEEKER: This big one isn't, but this  
17 one over here, which looks like it's fallen over, it  
18 is.

19 AUDIENCE MEMBER 4: I understand. Yes.

20 GREGORY MEEKER: So for years the toxicity of  
21 asbestos has been attributed to the special properties  
22 of commercial-grade asbestos -- tensile strength --



1 when aspect ratio, curvature, and chemistry of these  
2 properties really only by an aspect ratio have been  
3 clearly demonstrating to correlate with toxicity.

4 We're working on this instrument now, and I  
5 hope to get it operational soon. (Audience laughs.)

6 So let's go back to that Zoltai paper, and  
7 this has been referenced numerous times over the years  
8 by many, many people; and we already looked at the  
9 first page, and this is a very long paper. It's 39-  
10 pages long. So when I first found this, I thought, oh,  
11 great, this is really gonna explain the difference  
12 between asbestiform and nonasbestiform particles.  
13 Well, you read the paper, and 39 pages later, this is  
14 all that is said -- (audience laughs) -- in that paper  
15 about the difference between why you need those  
16 properties for toxicity. That's the end of the paper.  
17 It references this Stanton and Layard. It's the NBS  
18 special publication 506. And you go to heating, there's  
19 nothing here either. I mean, this is all you get. If  
20 you heat it up high enough, it's not as toxic.

21 AUDIENCE MEMBER 5: It's not asbestos then.  
22 It's another mineral.



1 GREGORY MEEKER: That's right. So here's the  
2 slide I stole from Aubrey Miller. I think it kind of  
3 sums up what we're talking about here. You've got the  
4 total respirable material. You've got the regulated  
5 asbestiform material here, and then you've got all this  
6 other stuff that's not regulated. It's not commercial-  
7 grade asbestos. What do you do with it? A lot of people  
8 believe that -- this and that and so can any doctor or  
9 toxicologist but believe that these things here are a  
10 problem. What does the lung know? What does the body  
11 know? I think that's the real question we're dealing  
12 with here, and I think as we move forward in any kind of  
13 effort to put together a statement or a summary for  
14 this, we have to keep this in mind.

15

16 So that's all I have. Thank you very much.

17 (Applause)

18 CATHERINE SHEEHAN: So next up I would like to  
19 introduce professor Martin Rutstein. He's a retired  
20 professor of mineralogy, teaching and research  
21 interests in: mineralogy, metamorphic petrology,  
22 optical mineralogy and environmental geology,

1 especially particulates and toxic chemicals; and  
2 presently co-chairs the U.S. Pharmacopeia Expert Panel  
3 on talc and asbestos in pharmaceuticals and is an  
4 expert witness in state and federal courts on asbestos  
5 and lead-based paints, so --

6 MARTIN RUTSTEIN: I guess I don't get to go  
7 for a bathroom break. (Audience laughs.) That's a lot  
8 to ask for. Let me just set the timer. Are we ready?

9 It's -- no, like this. We're just saying. I  
10 know where the mic is.

11 CATHERINE SHEEHAN: Okay.

12 MARTIN RUTSTEIN: There's going to be a -- she  
13 got me all set. We'll go back to that. Okay.

14 When I got the call, "Would you talk? Would  
15 you like to talk?" oh, yeah. Sure, I would love to  
16 talk. (Audience laughs.) They said, "This is what  
17 you're going to talk about," four things, which  
18 injected a tremendous --

19 You gonna fix this thing?

20 -- which injected --

21 TIM: Yes.

22 (Background noise)

1 TIM: Will you test it?

2 MARTIN RUTSTEIN: Okay.

3 MAN: Sure.

4 TIM: All right.

5 MARTIN RUTSTEIN: Here we are. Okay.

6 Which injected, immediately, controversy over  
7 limitations, damages. Mickey was beside himself. If  
8 you're there, Mickey, on the webinar, ha-ha-ha.  
9 (Audience laughs.) I took -- I listened, to you  
10 honest.

11 So I'll tell you how I picked the topics. I  
12 didn't even know who I'd be talking to. It started  
13 off, is it going to be done with regulators? Would it  
14 be people who are wizards in this? Some division -- I  
15 had no idea. It wasn't until just a few days ago that  
16 I finally got a handle on who would be in the audience.  
17 I've been working on this for some time. I think I've  
18 tailored it in a way that you'll all get something out  
19 of it.

20 My life has largely been teaching students and  
21 also out in the real world where somebody does  
22 something about asbestos, in terms of containment. I



1 dare say to Brad, I probably spent more time in  
2 containment than him and anybody in this room. It's a  
3 different world out there from the laboratory. I also  
4 headed up a NVLAP/ELAP lab, so I know my way around a  
5 laboratory.

6 So how do we measure and characterize the  
7 elongated stump? Before Brad jumps up and down on this  
8 one, we never use "elongated." Beat that into him. It's  
9 elongate particles. So we're really looking at these  
10 things that are longer, and let's talk -- I'll talk  
11 about those. I've got a lot of stuff to do, a short  
12 time to do it, so let's get on it.

13 First, there's some really smart people that  
14 I've had the honor to work with -- the USP panel. The  
15 first one, I put it on the reference list, the first  
16 stimuli article. It's really worth looking at. Five  
17 years of heavy intense work from really bright people.

18 The second panel, many of you are here. I  
19 thank you. It's because of you if I seem further, it's  
20 because I've stood on their shoulders; and some of them  
21 people are so darn smart when it comes to analytical  
22 work that I find it scary, and they were fortunate.

1 They have some of the best instrumentation going. I'm  
2 talking as an individual, not on behalf of USP. They  
3 drill into us every meeting we have that the meetings  
4 are confidential, they're works in progress, it's where  
5 we're going; and I think probably three years into this  
6 -- or two and a half years -- and were able to get a  
7 stimuli article on methodology published. At the  
8 beginning I said we had a certain amount of time to do  
9 it in.

10 Okay. Their idea, the first one.  
11 Mineralogists, it's like the cowboys and the cow have  
12 been in this sprint for decades on whose language,  
13 whose words we use. There are thousands of minerals,  
14 and mineralogists have their own cult, in terms of  
15 understanding the words we use and then often not the  
16 same that the regulatory community uses or that  
17 biologists use.

18 We go at minerals to identify them, and we  
19 characterize them. We do it on the basis of structure  
20 and composition. And probably, if you're interested in  
21 this two-page summary from Micky's and Gabby Diers's  
22 (ph) book, 2008, it's posted as a reference;

1 and it's really worth reading if you want to understand  
2 the side of the geological and mineralogical community.  
3 Not all of them. We all differ. We disagree. We  
4 argue. It's a pretty good summary on how we identify  
5 minerals.

6           However, asbestos is also defined as the  
7 regulatory six. We all know those. We dream about  
8 them. We eat, sleep and -- we know them so well. I  
9 like the sum that Brad just did on -- or Greg did on  
10 the chemistry. In one version of this presentation, I  
11 got over 50 tremolite mineralogical cousins based upon  
12 the Leake classification -- name after name after name  
13 after name, and it really is messy.

14           We have the regulated six, and I'm working off  
15 those. That's what's in the regulations that we have  
16 to live with -- chemistry and usage, also shape and  
17 size. The standard five microns long, bla, bla, for  
18 the long asbestos fibers. You don't regulate the short  
19 asbestos fibers, but they're out there. They're at one  
20 end, and then we've got the cleavage fragments at the  
21 other end and this EMP thing that we'll talk -- I'll  
22 talk about in a little bit too.

1           We also define asbestos medically and  
2       bioreactivity. I've come a long way over the decades.  
3       I've looked at this. I did my first asbestos  
4       inspection in 1972, before many of your parents were  
5       even born. I looked at this stuff in the field, I've  
6       look at it in the lab, and more and more I'm evolving  
7       toward: What's respirable? What gets into the body?  
8       What can cause harm? But we have to live within the  
9       rules of what's regulated.

10           We also have this characteristic of a motion.  
11       I can empty a building by saying, "Asbestos is falling  
12       down from the ceiling." People have been convinced --  
13       it's almost a religious thing, good versus evil --  
14       asbestos is bad. There's very little debate out in the  
15       public area, and I think that one of reasons the jury,  
16       say, in St. Louis are coming down so hard against  
17       Johnson & Johnson is because they hear the word  
18       "asbestos" and right away the bell goes off -- bad,  
19       death, evil, punish somebody.

20           I put together these several pictures of  
21       different materials: talc ore; talc powder, the  
22       products; and then, from Brad, some of the stuff from



1 Death Valley; and the calcium amphiboles. In 2007,  
2 Dodson came up with 30 different analytical methods for  
3 asbestos. The number's even larger now. If you do a  
4 search and you spend the time -- is Ella (ph) here?  
5 Ella, is she at break?

6 AUDIENCE MEMBER 6: Yes.

7 MARTIN RUTSTEIN: Thank her. You know, you  
8 put together that list on the definition of "pride."  
9 It was you, wasn't it? Or was it Lee (ph). It was  
10 Lee. Sorry, Lee.

11 AUDIENCE MEMBER 6: Go get after him.

12 MARTIN RUTSTEIN: Get after him for all of us.  
13 (Audience laughs.)

14 But the list goes on. Hey, I got -- Friday  
15 one person says, "Well, I've got asbestos." Another  
16 person says, "I don't have asbestos." They used two  
17 different methods, and they're not communicating; and I  
18 hope to convince you that that's one of the really  
19 important goals that we have to come up with is a  
20 definition that we agree on.

21 The big issues, as I see it, are these  
22 elongate particles, the so-called EMPs: talc,

1 tremolite, anthophyllite. Chrysotile, I worry less  
2 about because I think it's so easily identifiable. I  
3 can just put it on the side.

4 I don't even put actinolite up because I think  
5 that's just a slightly ironness tremolite. There's  
6 also a lot of other minerals, especially sepiolite; and  
7 one of Mickey's grad students, Marian Buzon, finds  
8 really neat fibrous sepiolite in some of the Montana  
9 mines which could mimic talc, which would mimic, maybe,  
10 anthophyllite.

11 The three categories of materials: the  
12 cleavage fragments, from a mineralogist, they're broken  
13 crystals. They start as big things and you break them,  
14 it's a cleavage fragment. How do we break them? A  
15 plate or weakness. That's all another source. It's  
16 just a broken fragment. The shape, acircular and  
17 prismatic. They're just shapes. We used to talk about  
18 them as just a morphology. That was a generalization:  
19 tall, short, fat -- I guess it's fat shape -- thin,  
20 whatever. Thin shape is so much later, but they're  
21 just general terms, and they've taken on to some as  
22 very important regulatory criteria. Talc (inaudible).

1           Then there's asbestiform minerals, fibers  
2       formed by crystal growth. I won't even touch getting  
3       into the finding of fiber. There are dozens of  
4       different definitions of that all depending upon the  
5       method that is being used.

6           So we've got to worry about cleavage, shape,  
7       and asbestiform materials. I've stopped talking about  
8       asbestiform talc, fibrous talc, because the word  
9       "asbestiform" immediately connotes something really  
10      bad and regulatable.

11          A couple of time symbols. What you see  
12      depends upon what you're looking from. There's a human  
13      bias on this. It's real. This is very important. I  
14      call it environmental outcome. If you change the way  
15      you look at things, the things you look at change.  
16      It's one thing to have it in hand sample where we can  
17      identify it; it's another thing to go through the  
18      microscope, another thing to go in an electron  
19      microscopy. Pretty soon you've got really good  
20      measurements at both ends of the spectrum but you're  
21      coming up with very different answers. What we find in  
22      most rocks is something elongated. It just happens,

1 the way it breaks. So it's a level of how much of  
2 something is something of concern.

3 Take a look at doctor's papers and Mary's (ph)  
4 papers, especially sepiolite on that one. He  
5 summarizes in a pre-notation to SME 2016 all the  
6 different deposits, and one of the things you should  
7 recognize is that the three categories: the regional  
8 metamorphic, the ultrabasic, and the -- the basic, the  
9 metamorphic and the --

10 AUDIENCE MEMBER 6: (Inaudible).

11 MARTIN RUTSTEIN: -- gabbro, the Death Valley  
12 types. Death Valley type, a single heating event. The  
13 regional metamorphic, multiple heating events changing  
14 of the character of the rock and real effects are water  
15 and carbon dioxide during their formation. So it's  
16 like boxing around when one mineral forms, and you  
17 really have to take that into account, along with the  
18 ultramafic rocks. In Vermont, they produce raisins --  
19 I mean prunes -- prunes are even a better for you now  
20 that you're a senior citizen -- mixed into a dough and  
21 then the dough is kneaded, and these individual masses  
22 -- the prunes and the raisins -- get cooked differently

1 and they represent a different composition. So you go  
2 to one deposit and you find one thing. You go to  
3 another deposit, you find something else, and the  
4 producer is mixing stuff from each deposit.

5 I thought it was critical. I loved Gouverneur  
6 Talc at one level. They were very kind to me over the  
7 years, letting me into their mines with my students;  
8 but the stuff over at talc mill was very different from  
9 the stuff at the iron pit; and for many years, without  
10 knowing this, I think was the case, they were mixing  
11 stuff in the talc fill. I went there one year, and I  
12 think -- actually, they were draining the pit; and I  
13 could see fibers blowing in the breeze. I went down  
14 and said, "You really don't want to start mining that  
15 stuff. Just cover it up." Some of the work that's  
16 been done on South Hill has been through surface  
17 samples. The stuff at depth in the literature is very,  
18 very different. They were bodies that were largely  
19 fibers of anthophyllite, contrary to what's on -- they  
20 use mining at the surface.

21 Building materials, I think, are really  
22 relatively simple. We put the stuff in. We have a

1 criteria of 1 percent, which was only adopted because  
2 most of the stuff is 10, 20, 30 percent asbestos. You  
3 can see it in the sample.

4 When I mentioned irrespirable, I thought of a  
5 funny sketch that I was doing in school where the  
6 student was sitting inside a pipe that had a magnesium  
7 block filler with cristobalite; and the student was  
8 spending the class time, not listening to the teacher,  
9 pulling out the blue fibers and going -- (blowing) --  
10 in the air. (Blowing) I had closed the room. It was  
11 very inadequate.

12 So building materials -- I would say that  
13 mineralogists, who's into asbestos, can identify a hand  
14 sample easily 80 to 90 percent of the asbestos that he  
15 sees just by a hand sample. Pharmaceuticals, much more  
16 complicated -- much more. If there's anything there,  
17 it wasn't put there deliberately or it was put there  
18 inadvertently, and it's much smaller, and you can't  
19 really see it most of the time in a hand sample.

20 So the definition of conundrums, as I  
21 characterize stana (ph), are mineralogical, industrial,  
22 regulatory, and legal. We have to agree upon some

1 method that gives us an answer that discriminates  
2 asbestos from nonasbestos particles, and you heard Brad  
3 and Greg pretty much address this issue. We got these  
4 things. What are they as we start to look at them with  
5 finer and finer analytical techniques?

6 Take a look, if you haven't seen it already,  
7 the papers by Gordon et al. against versus R.J. Lee and  
8 Drew Van Orden. I slugged through these papers, and at  
9 first, this guy is right. This guy said, "No. He's  
10 wrong." And this guy seems right. This guy says, "No.  
11 You're lying. You're wrong," and it goes back and  
12 forth. Have a bottle of Advil right beside you as you  
13 go through it. (Audience laughs.) That illustrates to  
14 me some of the profound questions are trying to come up  
15 with the answer for the property owner, a building  
16 manager, a miner, and a government regulator.

17 So which method is best? Go to all types or  
18 tab asbestos four. The alphabet soup, for anyone who's  
19 into this -- and I'll explain one of them -- each has  
20 individual and corrective advantages. Each one is  
21 unique in its own way. Here's a -- fundamentally, in  
22 geology and mineralogy we teach students to identify



1 hand samples. Mickey, in that chapter 19 introduction,  
2 says that's really -- if I understood it right, not  
3 completely adequate. You need more sophisticated data,  
4 chemistry, and structure. I think that a large part of  
5 traditional mineralogy and probably part of the core  
6 arm of this disagreement with some of the regulators  
7 and biologists has been that geologists will take  
8 something that they know is fibers -- you can see it.  
9 You can roll it between your fingers. You can take a  
10 torch or a barbecue lighter, try to burn it. A really  
11 convenient field method -- we do it all the time in the  
12 field -- is to take building material, hit it with a  
13 flame; and if there's something left over that we can  
14 rub and ball up, it's almost certainly going to be  
15 asbestos.

16 I'm looking over here at some fibrous talc.  
17 It's that picture that is -- whether it's  
18 anthophyllite, asbestiform going to talc, as some  
19 believe, or nonasbestiform anthophyllite going to  
20 asbestiform or fibrous talc, as others believe, is  
21 really the heart and soul in this. I look at this under  
22 the microscope. I look at the images that

1 others have taken with TEM, and boy, some of them really  
2 walk and talk like anthophyllite being asbestiform.

3 Then there's this stereo zoom microscope.  
4 Remember in '79 arguing with the people who were writing  
5 the original RE's book on methods for hand sample  
6 analysis building materials. Saying, "Look at it with a  
7 stereo zoom scope. You can see so much. Even for some  
8 of the talc products you can see them prismatic. You  
9 can see light coming up at you from a prismatic  
10 fragment," and I am going to move more and more toward:  
11 If you have anything, you're probably going to have  
12 aggravation. So maybe that's the goal is to find  
13 products that don't have any amphiboles.

14 Optical microscopy. Two major methods: the PCM  
15 and the PLM. PCM industrial site. Their samples gave  
16 us lethargy and as Dan Prey (ph) always says to me and  
17 to colleagues when we're talking: This is what's  
18 regulated by Government -- the federal five, the 3 to 1.  
19 PLM, this is a really useful technique from building  
20 materials -- polarized light microscopy. This one you  
21 actually get some clue from structure  
22

1 decomposition. This one clearly is interference by  
2 defect -- right interference defect where you just see  
3 shapes. So the way I might go with this with you is  
4 that I'll march through the different methods -- PLM,  
5 polarized light microscopy -- and let's talk about  
6 advantages and then quote something more than  
7 disadvantage. The big thing about light microscopy,  
8 PLM, it's coded. We have rules, and it's wide spread.  
9 Any lab who's doing asbestos has the PLM, and sometimes  
10 they have people who have been trained with courses in  
11 polarized light microscopy. Other times we're taking a  
12 shake and bake. Unfortunately, in the geologist  
13 community more and more universities are getting rid of  
14 light microscopy as a course saying instead let's go to  
15 the TEM, the SEM. Let's go to more sophisticated  
16 techniques because this is an old fashioned technique,  
17 but boy, it really works. It's especially good for  
18 building materials. So I give it, on the scale, a  
19 really high grade. It's up in the green. It's a  
20 pretty good technique.  
21 Then instead of just disadvantages or limitations, I  
22 describe it as issues along with disadvantages. One of



1 the big criticisms on PLM has been its magnification  
2 limit -- 400. If the wind is blowing right, maybe you  
3 can get up to 450 and hope you see something; but  
4 there's really anything to me beyond 3'-350 you go  
5 easily in the wind. However, that quantification is  
6 improvable by techniques such as sieving quality  
7 nitration and you can probably -- as someone told me,  
8 they can get down to a detection with 100 parts per  
9 billion on polarized light microscopy which is really  
10 pretty good because 100 ppm or something probably  
11 doesn't have a whole big effect on human health. At  
12 least I would gladly be exposed to 100 ppm if I had to.  
13 It just doesn't concern me when I look at the  
14 regulatory limits of what we can have in an industrial  
15 workplace.

16 So I'm not going to talk about all these  
17 things. Look at them. I showed them to you. There on  
18 the notes that I posted, and if you're into PLM, we can  
19 talk about these at great length; but the big thing to  
20 me are the disadvantages -- its supposed limitation. So  
21 I give it not so good a score. This is Dancing with  
22 the Stars kind of thing. You moving over but you can

1 correctly bring it back if you do this.

2 Then we get to high-tech instrumentation or  
3 the stuff that's out there now and clearly unamazing.  
4 We have x-ray diffraction from structural fingerprint,  
5 and we have electron microscopy that will give us  
6 structure and chemical analysis all of which has to be  
7 done right. The advantages are extra. It's fast. I'm  
8 getting -- I'm trying to convince Carlisa (ph). The  
9 minute you get a sample in, the first things you do is  
10 look at a PLM and while you're looking up there trying  
11 to make up your mind, do a scan, do an XRD scan of a  
12 certain portion of the spectrum -- of the angular  
13 region of interest and look at both of these states  
14 together.

15 So it's fast. It gives you gross ID. You get  
16 much of the minerals that are present, and you can  
17 improve it again by concentrating the sample and  
18 adjusting the scan speed. So we'll give it a good  
19 grade from XRD.

20 The disadvantages, there's a lot of  
21 aggravation if you have an X-ray machine: radiation  
22 protocols, you need to the calibrate the machine to the

1 standards, etc., and it gives you very poor shape  
2 information. Back when the pre hero rules were being  
3 written, X-ray was really omitted. Why? Because it  
4 didn't tell you anything about shape, so people just  
5 pushed it aside, and it lost a lot of its relevance. I  
6 think it's coming back now because it gives you a quick  
7 answer in the case of talcs over whether there are  
8 other minerals concerning them.

9 The two issues that I'll talk about are  
10 overactive beats and detection levels, and they are  
11 really both the same which will allow us to raise the  
12 negative score to something that's better.

13 So here is a measuring fractured scale taken  
14 at (inaudible), and the critical point is right about  
15 here. There's an amphibole at 2 degrees -- two  
16 category, 2 degrees to fail, and it's very hard to see  
17 because the talc peak is masking it. So the way you  
18 can get around that is just to do a slow scan -- the  
19 talc peak stands out and the amphibole peak right here  
20 on the shoulder is identifiable at 10.2. So you can  
21 see if you've got amphibole in your system, but right  
22 away we've got two techniques that work very, very



1 quickly and independently of one another: the PLM to  
2 see whether you have any fibers. You push it in and  
3 out when you measure and the inside (inaudible), and if  
4 you've got amphiboles, they know you have aggravations.  
5 Then you can immediately decide: How far do I push the  
6 envelope on this before rejecting the material as a  
7 product?

8 SEM. SEM is another one that is our very  
9 history. When we first started in the '70s looking at  
10 this, people loved SEM. It was a great machine. You  
11 could see the shape beautifully. You could get  
12 analytical information, and I gave it a high score.  
13 However, SEM, because it had no structural capability,  
14 when AHERA came out, it was pushed to the side because  
15 AHERA and TEM. TEM was perceived gold standard. That's  
16 the one we should use. So I don't argue that SEM has a  
17 very important place just seeing what's actually in  
18 there. It's just increasing the magnification from  
19 PLM, and you get a quick answer if you have any fibers  
20 or elongate mineral particles. So the negative score  
21 is because the perceived conflict with TEM under a  
22 hill.



1           TEM. We can get great prevention from  
2 morphology, chemistry, and structure. We distinguish  
3 the amphiboles species if done right, and it's perceived  
4 as the AHERA gold standard. Remember that TEM, under a  
5 hill, was designed for asbestos abatement or remediation  
6 projects. It was designed to look at the particles that  
7 would be left over, if at all, in the air from the  
8 removal of asbestos. It didn't open up the water to  
9 look at any EMP. The rules were codified to look for  
10 residual asbestos to signify that the cleanup was not  
11 going accurately. So it has a really good story.  
12 However, there were disadvantages too. And the  
13 disadvantages are endurance of the interpretation of the  
14 shapes. You saw that a few moments ago with the tossup  
15 thing. What is this elongate thing? The population, is  
16 it detected? Is it confirmed? What does milling do to  
17 it? How do you change it from the product as it was put  
18 out for sale versus what we do in the laboratory? And  
19 very importantly, this talc versus anthophyllite -- that  
20 kinky talc. I wanted to get up here with red kinky  
21 boots to put up there, but I thought that would be  
22

1 pushing the issue too much.

2 Kinky talc is twisted talc. And there's a  
3 reference that I will call to your attention. I don't  
4 have it here. There's a reference that I will call to  
5 your attention in a few moments by Jim Millette where in  
6 his last -- the last page of it, he defaults on twisted  
7 talc 25. I think this is a real concern, and it's  
8 generated a lot of controversy between people who agree  
9 with him, people who don't agree with him. So let's look  
10 at that one.

11 If you have a single fiber or just two fibers,  
12 how many fibers are too many? How many fibers are  
13 acceptable? How do we deal with just a few fibers  
14 compared to looking at something you can hold in your  
15 hand and you know it is definitely asbestos because you  
16 can look at all the classical products. It's likely to  
17 be asbestos on the basis of these factors. The aspect  
18 ratio, whether it's 3 to 1 -- which I don't like, but I  
19 understand it. Going out as the others shown, you  
20 really need 20 to 1 or greater. You need a large  
21 population. You can't just look at one.

22 Now, in a PLM, you've got a whole bunch of

1 fibers, a whole field of viewers. We're on step. It's  
2 just not a problem. If you're looking at otomicroscopy  
3 then we have a few fibers down here, then it becomes an  
4 issue. The geometry, the power of size, determination,  
5 the end; and some of these come down to just judgment,  
6 as you saw -- as I mentioned a few moments ago. Truly  
7 a judgment on whether it's a cleavage fragment, whether  
8 it's asbestiform.

9 And then there's nomenclature. Nobody saw  
10 leaky at all with the multiple divisions are amphibole  
11 nomenclature. We have so many things out there in  
12 nature and rocks that would fit as being cousins to  
13 tremolite or even some of the amosite minerals, but  
14 I'll stay with tremolite because -- and anthophyllite  
15 because we're into calcium-rich systems.

16 Litigation is driving a large part of this.  
17 The realities to me seems to be that if you got law  
18 cases being won with huge sums of money being awarded,  
19 people will start to say, you know, I'm gonna get in on  
20 the business -- like bad people. John? (Audience  
21 laughs.) But you know, they're going down the road  
22 saying, "This is what I asked to show," and sometimes

1 the evidence gets interpreted based upon pride and  
2 reception. We scientists like to think we're pure and  
3 good, but sometimes bias does creep into it.

4 The chemistry issues and -- the reason for the  
5 crazy fuzziness there is that they switched them back  
6 from PC. If you look at anthophyllite talc and  
7 tremolite, tremolite is really easily distinguishable  
8 because it has calcium. Calcium is a talc and  
9 anthophyllite is infinitive. You've got all this  
10 calcium. So if you're seeing calcium on the spectrum,  
11 you can be pretty sure that it's going to be tremolite  
12 if it fits the other criteria. Anthophyllite and talc,  
13 however, are a little bit of a problem. The ratio  
14 between calcium and magnesium for both of these is  
15 very, very similar. So there are some talcs which  
16 could appear both logically like anthophyllite and the  
17 chemistry seems to be the same, and this was the  
18 problem that I saw with Merlet. So it takes real work  
19 to distinguish anthophyllite from talc.

20 Take a look, if you're at all plugged into  
21 this. It's only to read a paragraph on -- let's --  
22 page 17, fibers with kinks. That if it has this

1 twisted characteristic -- and Garret's arm is showing  
2 you a lot of pictures of twisted fiber. We're calling  
3 it -- he's calling them "rivets," and they twist; and  
4 if you look at them, they can turn out to have a  
5 different interpretation unless you connect the dots  
6 right. So the issue is this 5.27, 5.27, 5.28  
7 dimension.

8 In a deposition once I got hammered by a  
9 lawyer saying, "What about the 5.28?" 5.3 I think is  
10 what he was saying. It's required to be able to  
11 identify the asbestos, and that's down 5.3. I know. I  
12 said so. "I really don't know what you're talking  
13 about." (Audience laughs.) And he went back and  
14 looked it up and scope with a gun to about this long in  
15 back. "What type of now?" It was like a golden eagle  
16 on this --

17 AUDIENCE MEMBER 7: It's as easy as ABC,  
18 right? (Audience laughs.)

19 MARTIN RUTSTEIN: Yeah, ABC. Easiest -- and  
20 the ABC, by the way, of the dimensions. We don't talk  
21 about knock down sideways. We talk about ABC unless we  
22 go into reciprocal space, and then it's XYZ, but you



1 guys -- you don't have no problem here.

2 So it's how you connect the dots in this  
3 twists talc, and it's not always correct to use just  
4 the 5.27. On this part too, here's a crystal  
5 structure. You'll get a tab, and here's one of  
6 anthophyllite and tremolite.

7 (Phone ringing.)

8 MAN: You're 30 minutes.

9 MARTIN RUSTEIN: Shut up. Go away. Stop.

10 On talc, same dimension. Same dimension. So  
11 you need two dimensions and one angle for the correct  
12 identification. And Matt and RJ Lee have published on  
13 this one, and this will clarify if done right on largely  
14 ambiguity.

15 So summary. There are limitations and  
16 advantages of a single map. There's no one size-fits-  
17 all. What we're trying to do is prove the absence of  
18 relevant amphiboles and chrysotile. That should be the  
19 overarching goal for us. We need a full spectrum of  
20 analytical tools to put together in this crossword  
21 puzzle. We need to be able to look at them with a  
22 common analyte definition. If we don't agree, on what



1 we're looking for, then the measurements become highly  
2 mental. One side is saying, "You're doing the wrong  
3 thing. Blah, blah, blah."

4 PLM will remain the primary technique, given  
5 its simplicity, and part of what we're doing is to find  
6 something for industry that they can really go with  
7 instead of having a whole separate analytical vat.

8 I think SEM will start to come back. SIB,  
9 especially useful. It's fast, down and dirty. You go  
10 through there with only about 5 degrees of stamp, and  
11 you're getting answer about amphiboles. TEM, likely to  
12 be the ultimate tool, but only, only if we can agree on  
13 the definition of making irrelevant shapes.

14 Prior to the meeting, the speaker sent in  
15 questions. I asked one question. Can we agree on some  
16 kind of definition? And the sponsors, the conveners of  
17 this, their answer was pretty much, "We don't think so,  
18 not in this short time." And if we want out of here and  
19 we don't agree, then we're going to continue the debate.  
20 Remember that under TEM (inaudible), you can use  
21 ambiguous in a determinant. This cartoon, three nights  
22 worth, I don't know. Throw the problem up to

1 management. Throw the problem to those who are  
2 deciding whether to use the product or not. It may be  
3 that our analytical techniques aren't good enough yet  
4 to decide what these things are. It takes it out of a  
5 whole realm of aggravation.

6 So going down with guard free and our patriots  
7 to the Wizard of Oz, the Emerald City as we seek the  
8 perfect method and we chase after analytical zeros  
9 because I can always measure it better. I can look at  
10 it smaller. I can do better, da-da, da-da. Make sure  
11 you remember as we go to utopia, we're looking at  
12 commercial progress. We're looking at minerals and  
13 they both vary in physical and chemical properties,  
14 what we're trying to measure. Watching what we did and  
15 watching what we're going. We're inheriting the wind,  
16 so to speak, because I'll get you because you didn't  
17 define asbestos clearly enough. This is a joke.

18 (Audience laughs.) We all remember the wicked witch  
19 and she's out to get us, and we didn't define it right  
20 because we were looking at stuff. We were looking at  
21 schools where stuff was falling down from the ceiling.  
22 We were looking at building environments where workers

1 were exposed. You can see the clouds of asbestos in a  
2 workplace, and I've been there and done that. I  
3 understand that, but I'm not so sure about these trace  
4 amounts, whether they really held any flag in trying to  
5 protect human health.

6 So looking back, which you get to do after you  
7 get older and you go on Social Security, you get to  
8 think a little bit about this life. You can't tell how  
9 deep a puddle is until you step into it. If asbestos  
10 is really as dangerous as many perceive, if it's  
11 ultimately the killer rock that they are asbestos, is  
12 it logical or bias that leads us to be concerned about  
13 EMPs? This is philosophical, but it's profound. Why  
14 are we looking at EMPs? Do we have the health data?  
15 Do we have evidence that this is something that should  
16 be of concern?

17 When I started with this decades ago, I should  
18 have paid attention to this part. I didn't, and I got  
19 trapped in asbestos muck in a mine, and I had to beg  
20 for people to pull me out. Now I look at the younger  
21 people now and I say, "You got to solve this problem  
22 because you've been handed really not a good plate of

1 material." And somebody somewhere has to be able to  
2 say, "Let's back up. Let's define what it is we're  
3 looking at and what we're measuring."

4 I'm urging some colleagues I'm working with  
5 now to say, "This is what we're going to take, yeah."  
6 Other people may disagree with that, but this is the  
7 rule. This is the regulation that we're looking at.

8 So any questions? (Applause) Thank you.

9 AUDIENCE MEMBER 8: I'm new to this and  
10 learned a lot. The question I have is which of these  
11 methods is quantitative?

12 MARTIN RUTSTEIN: Quantitative?

13 AUDIENCE MEMBER 8: Yeah, because that's --  
14 you know, TMS, CM --

15 MARTIN RUTSTEIN: They're all quantitative. You  
16 can make them all quantitative. You can make PLM easily  
17 quantitative by doing point counting, looking at the  
18 number particles in the field of view, whether you were  
19 looking at four slides or two 400 points or 200 points  
20 or 100 points. You can quantitate very easily with  
21 optical microscopy.

22 SEM, I don't think so. TEM, it depends on the

1 number of points you count. Do you count or do you see  
2 something? The XRD is easily quantified. You can set  
3 up standards and go with that and Gary may want to talk  
4 with you. He might be out. Gary? Gary has done some  
5 really fine work on quantitation with metrics.

6 Anything else? Yes, sir.

7 AUDIENCE MEMBER 9: When you say that that's -  
8 - I'm sorry. Thank you very much for the talk and the  
9 document about Canada.

10 MARTIN RUTSTEIN: Thank you. Hey.

11 AUDIENCE MEMBER 9: I'm sorry?

12 MARTIN RUTSTEIN: I was talking to me.

13 (Audience laughs.)

14 AUDIENCE MEMBER 9: Oh, okay. When you say  
15 that TEM is essentially the world standard, PLM it will  
16 probably be the primary technique, I guess the part  
17 that we struggle with is that the two are not  
18 necessarily looking at the same thing with both, so --

19 MARTIN RUTSTEIN: It was PLM and what?

20 AUDIENCE MEMBER 9: Well, using PLM while I  
21 was sad for TEM. You're not necessarily getting the  
22 same results with both, so --



1 MARTIN RUTSTEIN: Right. Because you can't --  
2 it's environmental alchemy. It's when you change the  
3 magnification, you're seeing something that it wasn't  
4 before. When you look at a hand sample, when you look  
5 at the chrysotile under a back light on fedra (ph), you  
6 don't see fibers. It can be 7-meters long and you can  
7 just ball it up. If you get out of your car, you can  
8 make a snow ball out of it and throw it, but when you  
9 look at electron microscopy, you're only seeing  
10 individual fragments, small; and I think we fail to see  
11 the disconnect between the two, so we have to be very  
12 careful, in my view, of how we interpret the TEM. The  
13 PLM is relatively easy.

14 AUDIENCE MEMBER 9: Well, because what we  
15 found is -- one of the huge challenges that we've found  
16 is something -- a sample that looks like it's really  
17 out, there's no asbestos whatsoever. You use PLM, all  
18 of a sudden you see and now there's lots of it.

19 MARTIN RUTSTEIN: And the crazy days around I  
20 hear are starting. The city of my kids, I walked in  
21 New York City. Shut down their water supply. They  
22 were taking it from the Hudson River and they said,



1 "There's asbestos in the intake in the water." And it  
2 turned out that what they were calling asbestos in the  
3 water was actually pond mar, which is no longer a  
4 mineral, but it's a common term. It's the black  
5 amphibole; and it was coming out of the iron ducts and  
6 it wasn't a health hazard but they were measuring it  
7 with TEM, and that's just part of the issue. What are  
8 we looking at, and is it something that we have to be  
9 here starting with exposure to human health? I think  
10 that's the bottom line. That's where I'm coming  
11 around, personally, on these EMPs in terms of --  
12 where's Ray? No, I was -- when he said, "What does the  
13 lung see?" I thought that was very profound. What is  
14 the body seeing on this one that makes it a problem?

15 So I -- just let me -- just get out there.

16 Mark? Is this Mark? Hi, Mark. Okay. Thank you.

17 (Applause)

18 CATHERINE SHEEHAN: Okay, Markey. We're doing  
19 pretty good on time, so --

20 So next up is Dr. Martin Harper, and he has a  
21 BS and MS in geological sciences and a PhD in  
22 occupational health in the London School of Hygiene &

1 Topical Medicine. He's a fellow of the Royal Society  
2 of Chemistry and the American Industrial Hygiene  
3 Association. He recently retired from the NIOSH after  
4 completing many projects and publications related to  
5 asbestos and other mineral particles, including being a  
6 co-author of the NIOSH roadmap.

7 So let's get you started here.

8 MARTIN HARPER: You know, I'm following on  
9 from I would estimate to be about 100 years of  
10 accumulated wisdom in the first three speakers. So if  
11 I sort of stall or stutter a little bit, it's because  
12 I'm already getting the I'm-not-worthy feeling. But,  
13 yeah, again, I'd like to thank, particularly, Nora for  
14 all her hard work; the JIFSAN organization for inviting  
15 me; and I hope I have something worthwhile to  
16 contribute.

17 As I said, most -- as I was introduced, most  
18 of the work that I've done regarding asbestos --  
19 practically all of it was done while I was at NIOSH,  
20 but I have now retired from NIOSH, and so -- why isn't  
21 this working? All right. So I got to put up this  
22 disclaimer. It says I am no longer speaking on behalf

1 of NIOSH or any other part of the Federal Government;  
2 and also, in full disclosure, I have never participated  
3 in any legal action with respect to asbestos or mineral  
4 products.

5 Now, the general characterization issues, as  
6 we've already heard, are the nature of some. I mean,  
7 we have so many different samples that we have to  
8 analyze for asbestos or other elongate mineral  
9 particles; and we're looking at those media with  
10 different purposes and different requirements, and so  
11 we often have to use different techniques that are  
12 appropriate to coming up with the answer that they're  
13 looking for; and so we need to ask questions like: How  
14 much of the sample is representative of the whole  
15 sample? So, for example, how many samples do you need  
16 to take in a talc mine to establish the absence of  
17 asbestos throughout the mine? You have, you know,  
18 veins of minerals that go through different properties.

19 I remember at one point I was going to look at  
20 a taconite mine, and I was told, "Oh, there's a vein of  
21 amosite going right through it." "Oh, yeah, but we  
22 avoid that." Really? Wow. Okay.

1           And there's a lot of different laboratories  
2     out there, and they don't all come up with the same  
3     answer all the time. How can we resolve that  
4     variation? When we're looking at particles, what's the  
5     minimum number we need for accurate characterization?  
6     And there are all kinds of issues of analytical  
7     calibration, proficiency testing, and reference  
8     materials; and this is all a bit of interest to me out  
9     of my analytical chemistry background. We can, again,  
10    as been noted, examine materials of different levels of  
11    magnification; and all of these have their own issues,  
12    different purposes and, therefore, also different kinds  
13    of quality assurance.

14           Looking at I4 and handlets, it's difficult  
15    sometimes to characterize things in the field. This is  
16    a serpentine outcrop in California, and as you start to  
17    look at it in a little more detail, you start to see  
18    things that are prismatic and even fibrous up here; and  
19    it's pretty clear that there's a range of morphologies  
20    spanning different fibrosities.

21           So what is the appropriate sample to determine  
22    asbestos component? Because even commercially

1 exploited asbestos partially include some material that  
2 might not be considered asbestiform. So we need to  
3 come up with some kind of sampling protocol. At least  
4 in the prior example you can see that some of the  
5 material is composed of elongate mineral particles and  
6 some receive an asbestiform, but as we've -- it's shown  
7 there are rock types that you can hit with a hammer and  
8 you don't necessarily know that they're composed of  
9 fibers.

10 How many particles do we need to examine?  
11 Well, it was reported at a Johnson conference a few  
12 years ago that even though UICCB, Chrysler power  
13 reference material was examined to the extent of 20,000  
14 fibers, that trace tremolite and amosite could be found  
15 -- tremolite at .045 percent and amosite at .003  
16 percent. Because it's a Johnson conference, I can't  
17 give you a reference. I can't tell you who said it,  
18 but it was there.

19 And how many particles do we need to measure a  
20 reproducible distribution? Well, I would say the bare  
21 minimum is 300, but really you need to measure about a  
22 thousand particles. It's kind of tough to do that on



1 TEM, especially when a lot of particles actually are  
2 longer than the field of view and they get outside the  
3 field of view. And for accurate chemistry? You know,  
4 I see people reporting at formulae two-three  
5 significant figures based on one EDS analysis. Are you  
6 kidding me? And with no attribute of uncertainty to  
7 that formula. Wow. You'd be dropped out of the  
8 analytical chemistry class for this, but I see it all  
9 the time.

10 So we also have this notion of fibrosity, and  
11 this has been popularized by Eric Chatfield (ph) and  
12 others to compare fiber dimensions of materials; but  
13 the -- you know, the preparation procedure is  
14 absolutely critical to the result that you get. What  
15 did you do to it? Jaw crush it? Did you grind it in a  
16 mortar and pestle? Did you put it in a jet mill? Did  
17 you sonicate it? All of these things will end up  
18 giving you a different distribution from the same  
19 starting material, and none of us really studied this  
20 to any great extent. But we have this comment, which I  
21 think was very appropriate, from -- from Sterling (ph)  
22 in 2010.

1           So if we're going to report fibrosity  
2     measurements, we really need to have a standard  
3     procedure to prepare the material prior to making those  
4     measurements. So this absolutely calls out for an ASTM  
5     Standard. Please, Frank, put it on the agenda. We've  
6     got to have this.

7           Now, there are existing reference materials;  
8     and this is the bulk of my talk now is the talk about  
9     reference materials and quality assurance, and there  
10    are some problems even with the existing materials.  
11    Take a careful look at the Wittenoom actinolite here,  
12    which is very nice and clean, and this UICC chrysolite  
13    here, which I refer to as a lollipop stick of gems.  
14    Little particles stuck to it, and all of this material  
15    that I've looked at from the UICC -- the amosite, the  
16    crocidolite, the anthophyllite -- kind of looks like  
17    this; and I thought, well, how come no one's noticed  
18    this before? So I went back to the original papers  
19    describing UICC material, and it dawned on me, they  
20    didn't have SEM. All those pictures are just under  
21    optical microscopy. You can't see this effect, but  
22    what's happened is because they jet milled it, some of

1 these longer fibers fragmented into tiny little pieces  
2 that then adhered, probably by electrostatic  
3 attraction, to longer fibers.

4 And you know, when you look at the Addison-  
5 Davis tremolite that was used in those experiments,  
6 they're all clean, just like this Wittenoom fiber here,  
7 because they didn't jet mill; and we know this because  
8 we also had a tremolite reference material, and we  
9 tried jet milling it, and guess what? It ended up  
10 looking just like this.

11 So NIOSH has a roadmap goal, a reference  
12 material repository for minerals; and I was working on  
13 that for a while, and ISO defines a reference material  
14 as "a material sufficiently homogeneous and stable with  
15 respect to one or more specified properties which has  
16 been established to be fit for its intended use in a  
17 measurment process." That's not -- sounds like  
18 gibberish.

19 And NIOSH has some reference materials of its  
20 own that were prepared many years ago by Fitree (ph).  
21 Not very many -- not very much of it left, and it's  
22 over in the Minerals and Materials Branch at the



1 Pittsburgh Mining Research Division now. And then  
2 there are some UICC reference materials still out  
3 there, but most of the remaining material got  
4 landfilled a few years ago. It all got transferred to  
5 the South Africa NIOH, and when they stopped receiving  
6 requests for it, they didn't want to keep it anymore,  
7 and so it's now down at the bottom of the landfill.  
8 They have a little bit left; however, you're the ones  
9 that are gonna have to figure out how to get it out of  
10 South Africa. They're still willing to give it away.

11 And then, of course, you know, there's been a  
12 lot of complaints that nice, common and uncommon  
13 materials, are no longer available; and indeed they  
14 weren't all -- all of them weren't all that good  
15 either. I mean, this is a photomicrograph of the nice  
16 tremolite asbestos, which has been criticized heavily  
17 for not being very asbestiform; and I'm comparing this  
18 with the tremolite asbestos that is the reference  
19 material of the Health and Safety Laboratory in the UK,  
20 and this is about the same magnification. So you can  
21 see there is a tremendous difference here.

22 The UK reference materials -- the Health and

1 Safety Executive, HSE, is the parent body of the HSA --  
2 of the Power for Safety Laboratory -- are described in  
3 a publication, and we wanted to see if we could get a  
4 hold of some of that. So we wanted to know where the  
5 tremolite asbestos came from, but the company person  
6 who donated the material to the HSE died, and the  
7 company had changed hands, and they had no record of it  
8 as well. All we knew was from this description that it  
9 came from the Salt Woods mine in southern California,  
10 and we couldn't find that in the gazetteer. We  
11 eventually found it. Brad Van Gosen was a great help  
12 in this because we identified it as coming from this  
13 Macaroy (ph) property, and here's the mine. I know  
14 several of you have visited it. I don't think there's  
15 very much left of this thing. Most of it's been taken  
16 out, and it was in the past sold to the Powhatton  
17 (ph) Company in Maryland for lab-grade asbestos, all of  
18 that stuff that you used to buy in the big jars from  
19 Baker and Mallinckrodt and so forth. And it's a very  
20 nice tremolite asbestos, and it's available from NIOSH.  
21 If you ask them nicely, they'll direct you to RTI who  
22 holds it, and RTI will give it to you. You have to pay



1 shipping I think, and that's a lot, like 50 grams. If  
2 I had known that somebody was selling the UICC stuff  
3 for \$1,000 a gram, I would have kept hold of it. It  
4 could have been my retirement. (Audience laughs.)

5 And like I said, this is what it looks like;  
6 but if you're jetting it, this is what it looks like.  
7 So be careful what you do with this stuff.

8 Another material that's going to come out of  
9 NIOSH shortly, I hope, is this one, an anthophyllite  
10 from the Percival Dunn mines in California that I  
11 collected, again, with Brad; and it's also a rather  
12 nice anthophyllite; but frankly, I'd rather get after  
13 this one, which is my favorite. This is the beekeepers  
14 anthophyllite fragments is what I'm talking about. One  
15 there. One there.

16 So then the other issue that we have to deal  
17 with is cleavage fragments and fine prismatic crystals,  
18 and the work that I've done on this has actually been  
19 through PCM of hair samples. And I know that's not of  
20 great concern to the audience here except that I think  
21 what -- my findings are relatable to PLM analysis,  
22 definitely; and the cautionary tale that I'm going to

1 give you is also relevant, I think, to SEM analysis.

2 And the reason that we were interested in  
3 cleavage fragments is because OSHA practices  
4 discriminatory counting, even though NIOSH and EPA do  
5 not, and there was an ASTM Standard under development  
6 D7200 with an attempt to codify discrimination; but the  
7 fact is, the procedure for discrimination really needed  
8 to be confirmed by an internal laboratory study, so I  
9 decided to do an internal laboratory studies. So for  
10 that I needed nonasbestiform amphiboles, and that  
11 wasn't actually as simple as it sounded. You got onto  
12 the mineral dealers, and you say, "Oh, give me, you  
13 know, a ton of riebeckite." They say, "What do you  
14 want that for? Nobody buys that." And I said, "Yeah."  
15 And then we found that things were not always what they  
16 claimed to be. So you know, we bought anthophyllite  
17 that turned out to be enstatite. We got tremolite that  
18 turned out to be inesite. And we ended up with five  
19 good minerals: Actinolite, tremolite, grunerite,  
20 brookite, and anthophyllite; but all the samples of  
21 anthophyllite that we examined contained that fibrous  
22 talc, and that's just in the nonasbestiform in Buffalo.

1           So in the work that we did, we used actinolite  
2     from Rockwood, California; NIEHS tremolite, which I  
3     believe came from New York; grunerite from Portugal;  
4     and riebeckite from Colorado. And these are pictures  
5     of them, and while some of them do appear fibrous, the  
6     fibers are really nonasbestiform.

7           And then we have to make cleavage fragments of  
8     a respirable size -- a respirable particle size. Well,  
9     that's not easy, actually. There's a sense that I get  
10    from people that as soon as you hit a massive amphibole  
11    with a hammer, you're gonna generate tons and tons of  
12    respirable sized cleavage fragments, and that's not  
13    actually the case. Most of the particles that are  
14    produced by Krishi, Megapee -- actually, eCORP -- and  
15    the fiber-like ones are pretty rare, I mean, about 1  
16    percent or so. And if I grind up the material where  
17    only 1 percent is my material of interest, I can't use  
18    that for tests. It's ridiculous.

19           So with RTI, we worked out a procedure to  
20    concentrate the fiber-like fracture; and RTI was able  
21    to make the 100- to 150-milligram quantities of these  
22    materials containing about 50 percent federal fibers. I

1 hate that word, that expression, but it saves me having  
2 to describe it further.

3 And so we used the tremolite, actinolite,  
4 grunerite, and riebeckite for the PCM round robin that  
5 we did; but tremolite and riebeckite cleavage fragments  
6 are also being used in toxicity tests at NIOSH right  
7 now; and I really hope that the results from those  
8 tests will settle some of the discussions that we've  
9 been having.

10 So this is an artificial creation of mind.  
11 The slides that we sent around to the different labs  
12 were dosed with different levels of asbestos fibers and  
13 the equivalent of cleavage fragments. So this is a  
14 photograph of the crocidolite and the riebeckite, and  
15 you can see sometimes it's pretty clear that that's an  
16 asbestos fiber. It's pretty clear that that's a  
17 cleavage fragment, but you know, what's this? I don't  
18 know. Is it a cleavage fragment or is it a show of  
19 part of them? No idea. Can't tell through PCM.

20 Now, the procedure for discrimination involved  
21 a subjective evaluation of morphology, and that was one  
22 of the things that we wanted to test. So we sent these



1 examples out to 11 laboratories, all of which, except  
2 mine, were accredited by the American Industrial  
3 Hygiene Association for asbestos analysis; and we asked  
4 them -- gave the set of slides to indicate all those  
5 particles which they thought met the morphological  
6 criteria for asbestos and which not. And this is the  
7 100 percent asbestos fiber slide, and this is the zero  
8 percent asbestos slide. These were all cleavage  
9 fragments, and you can see that the -- yeah, the  
10 results are all over the place. Here, we've got one  
11 lab that correctly identified 96 percent of the  
12 asbestos fibers as asbestos but; look here, two  
13 percent; and same with cleavage fragments. You know,  
14 we have labs that correctly identified, you know, zero  
15 or near zero asbestos particles in the cleavage  
16 fragments; but here, look at this level. So you know,  
17 it was very subjective. It could not be done, in my  
18 opinion.

19 What we did find is if we looked at width  
20 distributions, a rather good discrimination, at around  
21 about 1 micron -- it was actually about .85 micron --  
22 gave us the best discrimination between our fragments



1 and our fibers. Now, you know, these were artificial  
2 creations, okay? So I don't know how this reflects the  
3 real world except that I believe Ann's gonna show  
4 similar data later on, and so I don't think it's far  
5 off.

6 And we found the labs could actually do a very  
7 good separation by width. In fact, it was about as  
8 good at 1 micron as it was at .85 micron. You know, I  
9 just like round numbers. And so this standard, which,  
10 by the way, is applicable to my two quarries only, it  
11 does currently include this width criteria of 1 micron,  
12 which does a pretty reasonable job of ensuring that we  
13 count asbestos. We can't completely clear the cleavage  
14 fragments of -- you know, out of this; but you know, we  
15 can err on the side of caution, which is always, you  
16 know, good public health practice.

17 Okay. There's some other proficiency tests  
18 out there. There's the NVLAP, the AIHA's bulk asbestos  
19 testing, and there's also the Health and Safety  
20 Laboratory Asbestos in Material Scheme, or AIMS, which  
21 I'd like to bring to your attention. It's asbestos in  
22 building materials, generally targeted to

1 identification and qualification greater than 1  
2 percent; but occasionally you get samples of interest  
3 to the folks here, I believe, such as round 62, which  
4 included a sample with .1 percent chrysotile and .1  
5 percent amosite; and these were not detected by several  
6 laboratories in the scheme. And that round also had a  
7 crushed marble containing wollastonite when many saw  
8 asbestos. Twenty-three of the labs, by PLM only,  
9 identified the wollastonite as asbestos, and even six  
10 with electron microscopy identified the wollastonite as  
11 asbestos.

12 There's another scheme that comes out of the  
13 Health and Safety Laboratory called the Low Asbestos  
14 Content Scheme, which I think would also be of interest  
15 to people here. And round two was a sample of talc  
16 containing wollastonite with no asbestos, and 18  
17 percent of the labs incorrectly reported the presence  
18 of asbestos.

19 Now, if you're a lab and you want to join  
20 these schemes, there's a little benefit to that. You  
21 can purchase the HSL reference asbestos samples,  
22 otherwise, you can't. They don't have very much of it

1 left, and so they're reserving it only for people that  
2 are in their schemes.

3 So there's some new asbestos standards that  
4 are being worked on. I call them "new" because, for  
5 example, this one was first initiated in 2010, which is  
6 not that new anymore. And this is my understanding of  
7 how these methods are, based on the minutes of the last  
8 two ASTM Committee meetings. I'm gonna be pretty  
9 interested in gathering a round robin here, and also,  
10 I'm going to be pretty interested in insurance round  
11 robin, which I understand he's going to be presenting  
12 it today at conference; is that correct?

13 AUDIENCE MEMBER 9: I am not certain if I will  
14 be or not.

15 MARTIN HARPER: Okay. These are quotes, by  
16 the way, out of the committee minutes of the April  
17 committee meeting.

18 AUDIENCE MEMBER 9: All right. This is ours.

19 MARTIN HARPER: Okay. So the future work,  
20 obviously, is to extend the number of materials  
21 available to include other minerals of interest, such  
22 as zeolites and clay minerals, and to characterize

1 those that we already have, particularly in NIOSH; make  
2 them available as analytical standards; use them in  
3 identification round robins. But I want to see them  
4 being used for hypothesis-driven toxicological studies  
5 to determine if our theories of disease induction and  
6 progression are correct, and then we can use the  
7 results to derive mineral-specific risk assessments.  
8 And as part of that initiative, I've been working, most  
9 recently, on fibrous glaucophane from California. This  
10 is the Calaveras stand, which some of you know and  
11 several of you have visited; and this is the rock at  
12 the Calaveras stand, but this rock is not pure  
13 glaucophane. It's only about -- I think about 60  
14 percent -- 70 percent glaucophane. There's other  
15 minerals, like lawsonite; and it's not that fibrous  
16 compared to this material, which I collected with Mark  
17 Bailey (ph) from Marin County, California; and it's  
18 really nicely fibrous, and it's about 85 percent  
19 glaucophane, and it's really interesting to use as a  
20 reference material and also to test our ability to --  
21 toxicity of elongate mineral particles. And you know --  
22 - oh, by the way, this is an undattee (ph); and this --

1 I think, clearly, some of it is definitely asbestiform.

2 And so this is what we've done to it -- a full  
3 mineral characterization. We've hit it with just about  
4 everything that we can think of, and I think this is  
5 what we need to do. If we really want to know a  
6 material well, then one technique; one single SEM  
7 analysis; one single EDS result; one single, you know,  
8 X-ray is not enough. And so we've done all this to it,  
9 and we actually had several disagreements. And I could  
10 discuss all this, but the paper has been submitted for  
11 publication, including calculating the potential  
12 toxicity based on a model from my colleague Alexandre  
13 Walteare (ph). And what I need now is for some  
14 toxicologists to step up to the plate and come and get  
15 some of this stuff to confirm whether the model is  
16 accurate or not. Please, please pick up stuff. Come  
17 and get it.

18 And then, you know, just to, you know, clarify  
19 that we can't use a single technique, this is a PCM  
20 photograph of an air sample from a talc mill; and I  
21 don't know what that is or that or that or that. You  
22 know, but these were some samples that we were taking



1 while the talc mill was open; and I bought the first  
2 set of samples back to the lab, and I prepped them, and  
3 I looked at them myself, and I immediately got on the  
4 phone to my guys working in the field, and I said,  
5 "Don't take off your powered-air purifying respirators.  
6 I don't care what they call these things. I just don't  
7 want you guys breathing them, please."

8 And then because it takes a village, I have to  
9 acknowledge -- and I -- even after I've written this, I  
10 realized I left at least three other people off, you  
11 know? And this list is -- and most of these people  
12 have worked with me at no cost to me; you know, it just  
13 blows my mind that so many people are so interested in  
14 this field that they're willing to give up their time  
15 and resources to help me in what I've done, so thanks  
16 very much.

17 (Applause)

18 And I still remember one said, "This is proof  
19 that asbestos is still used in construction."

20 (Audience laughs.)

21 CATHERINE SHEEHAN: We have plenty of time for  
22 questions. So do we have any questions at this point,

1 Greg?

2 GREGORY MEEKER: Yeah. I'd just like to say  
3 the process of making a standard, and you said it  
4 either way, is -- it's so difficult. USGS did it, and  
5 I never want to do that again. It was a terrible job,  
6 and using every technique you can bring to the table to  
7 understand what you have is so important. Thank you  
8 for setting them.

9 AUDIENCE MEMBER 10: I really liked the  
10 pictures of the fibers that have been jet milled that  
11 had on it what you called "Jimmies."

12 How much of an effect do you think this has on  
13 the results we're seeing from toxicology using milled  
14 fibers versus --

15 MARTIN HARPER: Beats me. I'm not a  
16 toxicologist. I wouldn't even begin to speculate.

17 AUDIENCE MEMBER 10: It just struck me though.  
18 If we're looking at something that's not necessarily a  
19 singular shape, we're making pronouncements about the  
20 shape relative to that, we should consider --

21 MARTIN HARPER: Well, the fact is, we did, you  
22 know, 30 years' worth of work on that stuff without

1 really understanding what it was; and that, you know,  
2 goes back to exactly Rick's (ph) point, that, you know,  
3 we got to know this stuff inside-out, backwards.

4 AUDIENCE MEMBER 11: Have you used any of the  
5 data from the tissue burden studies to evaluate these  
6 dariets (ph) you're looking at in terms of toxicity and  
7 biological potential?

8 MARTIN HARPER: I'm not a toxicologist. It's  
9 not my field. Other people can do that too. I don't.

10 AUDIENCE MEMBER 11: Did you know Molly  
11 Newhouse (ph)?

12 MARTIN HARPER: Oh, yeah. She was in the  
13 department while I was there.

14 AUDIENCE MEMBER 11: The golden age.

15 MARTIN HARPER: Yeah. Oh, it was great. It  
16 was amazing. Charles Rossiter (ph) and Cole Coldest  
17 (ph). It was great.

18 AUDIENCE MEMBER 11: You mentioned the UICC  
19 samples. UICCs were blends. They were blends from  
20 different mines, for example, Chrysler (ph) Town UICC  
21 beats Canada.

22 MARTIN HARPER: Right. Right.

1 AUDIENCE MEMBER 11: And it's a blend from  
2 nine different mines based on the production figures  
3 the year that this formulation was --

4 MARTIN HARPER: Yeah. But I'm not so sure  
5 about the others. You know, UICC a Chrysler Power came  
6 from --

7 AUDIENCE MEMBER 11: Rhodesia.

8 MARTIN HARPER: Rhodesia.

9 AUDIENCE MEMBER 11: Michelle D. Anderson  
10 (ph), yes.

11 MARTIN HARPER: And I don't know if that came  
12 from multiple mines or not. So I -- yeah, definitely B  
13 was a blend, but I don't know what the other two is.

14 AUDIENCE MEMBER 11: Yeah. Chris Bodanic (ph)  
15 experimented with the nine separate blends, and he got  
16 nine separate biological assets.

17 MARTIN HARPER: Right. But that -- like I  
18 say, they were all jet milled to produce respirable  
19 fracture.

20 AUDIENCE MEMBER 11: Yes. Yes. Jet milling  
21 in the introduction of metal particles was also an  
22 interesting hypothesis --

1 GREGORY MEEKER: Excellent.

2 AUDIENCE MEMBER 11: -- that was raised.

3 MARTIN HARPER: And also the amosite  
4 contamination is in all of them, which means it's  
5 probably a carryover from, you know, one batch to the  
6 next, I'm sure. But then the Addison-Davis materials,  
7 the tremolites, were not jet milled. Those pictures  
8 all look nice and clean.

9 AUDIENCE MEMBER 11: Yes.

10 MARTIN HARPER: And so, you know, you've got  
11 to understand the materials and how they got to be what  
12 they are. It's how you use them.

13 AUDIENCE MEMBER 11: Is the NIOSH study an  
14 inhalation study?

15 MARTIN HARPER: No. You know, 100-150  
16 milligrams, it's not enough for a inhalation study.  
17 It's a study of variscite, and there may be a road  
18 terminal study. I can't remember now. The NIOSH guys  
19 might be able to tell you.

20 AUDIENCE NUMBER 12: There's nothing specific  
21 about jet milling, right? Like probably any milling is  
22 coding the fibers with those --



1 MARTIN HARPER: Well, the way it was done by  
2 Addison-Davis was to use a copy trail, you know, the --

3 AUDIENCE NUMBER 12: Yeah.

4 MARTIN HARPER: -- the rotary chocolate.  
5 Okay.

6 AUDIENCE NUMBER 12: And any milling. The  
7 pictures have me thinking, you know, the effect it's  
8 probably having on --

9 MARTIN HARPER: Well --

10 AUDIENCE NUMBER 12: -- the energy dispersive  
11 spectroscopy too, you know, so --

12 (Crosstalk)

13 MARTIN HARPER: The problem with the jet mill  
14 is that the fibers end up hitting the walls and  
15 breaking up. When we decided to try to reproduce the  
16 UICC for the tremolite, we bought a jet mill; and we  
17 started off with just glass fiber because we didn't  
18 want to contaminate the whole lab, and we wore away the  
19 jet mill just with glass fiber. We had to get a  
20 specially made silica carbide insert in order to be  
21 able to do any jet milling. And then this is what we  
22 got out, you know, those lollipops and cheerleaders is

1 what we got out of this.

2 CATHERINE SHEEHAN: Brad?

3 BRADLEY VAN GOSSEN: I may be getting ahead of  
4 the schedule a little bit, but in the talc cosmetic  
5 issue right now there's a lot of analysis being done of  
6 the product, but how much of the raw ore is being  
7 redone?

8 MARTIN HARPER: I don't --

9 GREGORY MEEKER: Can you repeat the question?

10 MARTIN HARPER: Yeah. The question was: How  
11 much of the raw ore is being examined in the talc  
12 industry? And I would suspect that, you know, people  
13 associated with the talc industry would be way better  
14 able to answer that than me. So is there anyone that  
15 wants to -- I know you --

16 AUDIENCE MEMBER 13: No. But I'd like to  
17 introduce a complicating fact. Most of the  
18 pharmaceutical-grade materials are actually blends from  
19 different mines, from both foreign and domestic.

20 MARTIN HARPER: Yeah, I'm not surprised.

21 AUDIENCE MEMBER 13: So the properties of  
22 color, lift, or fragrance, other properties -- skin

1 modification and chemical -- they all play some  
2 interest role.

3 MARTIN HARPER: And I mean, it's one thing if  
4 you're in charge of your own mine in the USA, and it's  
5 another thing when you're dependent on analyzing some  
6 bulk carbo product from some other country and how that  
7 varies from day to day, batch to batch, and then so on.  
8 I think Matt was going to say something though.

9 MATT SANCHEZ: Yeah. I can't be too specific.  
10 I guess it would depend on the talc mine company, what  
11 their internal procedures are; however, it's open to  
12 some companies. I know they're not even mining  
13 companies. Those that would use talc, get their  
14 plastics, ceramics, or cosmetics, it's not unroutine to  
15 actually go to the mines independently and do full  
16 assessments of the mining properties as well as ongoing  
17 quality control of talcs before they're shipped, before  
18 they're accepted by companies. But again, it's going  
19 to be company-specific how detailed they are. Some are  
20 probably not doing anything; others are doing a whole  
21 lot. It would really just depend on who the actors  
22 are.

1 BRADLEY VAN GOSEN: Yeah. That was probably  
2 where I was going with this important talc. Just  
3 curious how much quality control is on every talc.

4 MARTIN HARPER: Well, you know, the other  
5 issue is that you can't prove an absence.

6 BRADLEY VAN GOSEN: Right.

7 MARTIN HARPER: Yeah. How many particles do  
8 you want to look at? Like I said, with the UICCB, they  
9 looked at 20,000 particles and found no amphiboles. By  
10 virtue of a pre-concentration technique, this other  
11 research finally found .045 percent tremolite. Well,  
12 is that acceptable, you know?

13 If I was a talc producer and somebody came to  
14 me and said, "Well, have you got any asbestos in your  
15 talc?" and I said, "Well, I've got .045 percent," you  
16 know, are they gonna buy it? I mean, what's --

17 AUDIENCE NUMBER 14: How can you have  
18 something that you analyze 20,000 particles and find  
19 zero and yet a half of percent of it is another phase?

20 MARTIN HARPER: Point .045.

21 AUDIENCE NUMBER 14: Let's say a half a  
22 percent for analytics, .45 percent.

1 MARTIN HARPER: Point zero.

2 AUDIENCE NUMBER 14: Oh, you're say 0.45?

3 MARTIN HARPER: Yeah. Yeah.

4 AUDIENCE NUMBER 14: So they should have found  
5 some of it in 20,000.

6 MARTIN HARPER: Maybe. Maybe --

7 AUDIENCE NUMBER 14: I mean, if they would  
8 have sensed it in the system.

9 MARTIN HARPER: Maybe. Well, you know -- I  
10 don't know because, you know, that study has not been  
11 published. So --

12 CATHERINE SHEEHAN: Hey, Martin, it's yours.

13 MARTIN RUTSTEIN: When the public pressed on  
14 the Johnson & Johnson business, I concluded that one of  
15 the reasons the jury has ruled against Johnson &  
16 Johnson was because they tried the strategy of diluted  
17 the ore. They apparently saw that they had elongate  
18 stuff in it, at whatever percent, so they mixed it with  
19 a lower concentration, thinking dilution would be the  
20 solution to pollution, but it came back to bite them.

21 I also suggested that maybe the way to look at  
22 what's in the ore would be to look at the sediment --



1 at the runoff from the ore piles from rain and snow  
2 melt because the smallest particles would be carried  
3 away from the pile, and it would be like sluicing for  
4 gold. You would be looking at those, and it would be a  
5 down-and-dirty way to see whether it was any percent.  
6 I think the answer is, if there's anything in there,  
7 nobody wants to buy it.

8 MARTIN HARPER: What I didn't -- in my  
9 original version of my presentation, I had slides, but  
10 I took them out, that described the fluidized -- they  
11 had a fluidized --

12 MARTIN RUTSTEIN: (Inaudible).

13 MARTIN HARPER: -- that's been segregated,  
14 which maybe we'll talk about too; and that is a way of  
15 releasing respirable fibers from a sample and  
16 concentrating them in a way that way you can seriously  
17 get down to .000 -- you know, four zero, 1 percent  
18 (inaudible). And you know, it's a process that I use  
19 to look at soils or ZMI periodine, and it was amazing  
20 how low you can go in that world.

21 MARTIN HARPER: That was published. In fact,  
22 there's -- what? -- three publications on the FDAS now.

1 Anybody that wants one of these, let you know or talk  
2 to Ed (ph).

3 AUDIENCE MEMBER 15: Yeah. You talk to Ed a  
4 little about the percent of asbestos or fiber or  
5 whatever. Could you describe if that is either -- is  
6 it a weight percent are you talking about or a particle  
7 count percent or a projected area percent?

8 MARTIN HARPER: It's basically a particle  
9 count that's been converted into a weight percent, and  
10 that conversion factor itself is full with uncertainty  
11 because you're making certain assumptions about the  
12 materials. Yeah. I mean, it's a -- and of course,  
13 when people report, you know, material as having, say,  
14 2.4. percent asbestos -- say it's a building material,  
15 okay? Did they ever report uncertainty with that  
16 value? Any of the labs here report an uncertainty on a  
17 weight percentage? Did anybody even try to calculate  
18 an uncertainty?

19 MATT SANCHEZ: Well, I think from  
20 accreditations, that they would -- you're supposed to  
21 report out a coefficient of variation for ranges, but  
22 that's it. It doesn't -- you don't apply those to

1 actually give an uncertainty of the actual measurement  
2 reported.

3 MARTIN HARPER: I think if you actually looked  
4 at the true uncertainty of the treatment, yeah. Okay.

5 MATT SANCHEZ: But the uncertainty is dealing  
6 with how the methods that were designed for like  
7 building materials quantify. They're either allowing  
8 for just simply a visual estimation, which is by  
9 definition subjective, yeah. Or you're doing something  
10 like a point count where you're only counting like 400  
11 nonempty points, which doesn't give you enough  
12 statistical counts to have any real bite, real meaning  
13 at any --

14 (Crosstalk)

15 MARTIN HARPER: Right. And some people have  
16 propose a thousand counts to --

17 (Crosstalk)

18 MATT SANCHEZ: You know, it only improves it a  
19 little bit.

20 MARTIN HARPER: Yeah.

21 MATT SANCHEZ: You really -- to really improve  
22 it, you're gonna have to get into the tens of thousands

1 to really get the -- your counts to get a -- to really  
2 get a tight measurement on that. But the other thing  
3 that can affect the point counts, which is very true,  
4 is if you actually go through and do point counting on  
5 something that is incredibly fibrous, like a -- just  
6 say like a reepa (ph) chrysolite and you compare it to,  
7 let's say, a nonasbestos ampha (ph) like tremolite  
8 count, the nonasbestos tremolite count is more -- that  
9 would be a more accurate estimate than the real fibrous  
10 material, because as you go through that area of  
11 percentages, those elongated particles -- those  
12 asbestiform particles either takes more area -- it  
13 creates area by them being so long as part of the  
14 count, so they look like they're bigger particles when  
15 you're just doing it by areas.

16 MARTIN HARPER: Yeah. This occurred when I  
17 looked at the arenite material that I collected from  
18 Rome, and when you crush it and you look at it under  
19 the microscope, it looks like it's all fibers, you  
20 know; and you -- by point counting you say, "Oh, it's  
21 85-90 percent fibers," but then when you calculate out  
22 the size of those fibers versus the size of the glass

1 frames that are in there too, it's suddenly only 30  
2 percent --

3 MATT SANCHEZ: Yeah.

4 MARTIN HARPER: -- by weight.

5 MATT SANCHEZ: And again, the higher the  
6 magnification you go on your point count, you minimize  
7 some of those effects, but --

8 MARTIN HARPER: Oh, yeah. Yeah.

9 MATT SANCHEZ: Because, you know, like --  
10 well, you'll be able to see the two --

11 (Crosstalk)

12 MARTIN HARPER: You end up only seeing five --  
13 that's right. Exactly.

14 MATT SANCHEZ: But the other issue -- point  
15 that's important is all these things, because a lot of  
16 times people talk about PLM being insensitive, but it's  
17 really not. The quantification techniques that are  
18 employed are very insensitive, but the ability for PLM  
19 to observe something, that's a very sensitive  
20 technique. And the real measure of a sensitivity of a  
21 method is the ability to see a particle in the total  
22 amount of particles analyzed. How many particles can



1 you see when you're analyzing something at 100 decks  
2 first then 400 decks, compared to analyzing a bulk  
3 sample by TEM where you're at 20,000?

4 MARTIN HARPER: Yeah.

5 MATT SANCHEZ: The TEM analysis, in and of  
6 itself, for bulk samples, you look at so few particles.  
7 It takes so much time to look at so few particles.  
8 Then you do these huge extrapolations up. So  
9 quantification by TEM, especially in bulk samples, is  
10 highly problematic. Again, when you see something is  
11 another issue; and then the identification of what you  
12 see is separate from this idea of quantification.

13 MARTIN HARPER: Right. But at the end of the  
14 day, if we have targets for trace analysis, we can  
15 confirmed that we have met those targets by the use of  
16 spike samples and round rock and (inaudible) spike  
17 samples. So by whatever technique we can use or  
18 whatever multiple techniques we care to use, at the end  
19 of the day, we can create samples of 1 percent, .1  
20 percent, .05 percent, .025 percent. We can do that.  
21 You know, even though they're not homogenous materials,  
22 there's enough experience and expertise in making

1 nonhomogeneous spike materials. We can do that, but  
2 just give us a target, and don't ask us for zero --  
3 (audience laughs) -- because there's no such thing.

4 MATT SANCHEZ: No. You're right.

5 MARTIN HARPER: A target means that there's a  
6 level of acceptability. Well, don't use the word  
7 "acceptability." Use the word "tolerability" so we'll  
8 tolerate this much. We won't say, "This much asbestos  
9 is acceptable."

10 MATT SANCHEZ: That's true.

11 MARTIN HARPER: Maybe we can say, "This much  
12 asbestos is tolerable in talc because" -- and then what  
13 you do is you do a risk assessment --

14 MATT SANCHEZ: Well, that's right.

15 (Crosstalk)

16 MARTIN HARPER: You know, based on that. But  
17 I mean, without that information, the analysts amongst  
18 are kind of blindly trying -- you know, give you what  
19 you want. Figure out what you want; and then the  
20 analysts will just take the best technology and best  
21 expertise, and we have been, and we can give you what  
22 you need or what you want.

1 MATT SANCHEZ: I think it's important too, if  
2 any result -- the result is only within the parameters  
3 of the test. You can't extrapolate beyond the  
4 parameters of the test.

5 MARTIN HARPER: Right. That is also true.

6 MATT SANCHEZ: But -- well, I deal with a  
7 world where people say, "Well, it wasn't detected;  
8 therefore, it must be very small amounts." And it's  
9 like let -- the test doesn't tell us that. All it  
10 tells you is what that test is designed for. So if  
11 people are looking at that, they have to understand how  
12 that data was derived and what the scope of the data  
13 is.

14 MARTIN HARPER: True.

15 MATT SANCHEZ: And you can't go beyond that.  
16 The data only tells us what's in the scope of analysis.

17 MARTIN HARPER: All of these tests are  
18 surrogates for actually examining particle by particle  
19 every particle that goes into a can of talcum powder.  
20 Everything is, you know, a surrogate because of that.  
21 That's the whole definition of sampling and a sample,  
22 and that adds to the uncertainty of the technique, but

1     uncertainty is inevitable. Of course, try telling that  
2     to a judge or a jury. Perhaps the reason I never have  
3     testified in front of the jury is because I never want  
4     to admit to practicing uncertain science.

5             (Applause)

6             CATHERINE SHEEHAN: All right. So we've  
7     pretty much caught up, and we are now ready to take a  
8     15-minute break -- maybe 17 -- but we will be back here  
9     at 11:00 a.m. In the meantime, I'm gonna find out  
10    where the breakout sessions are being held, and I'll  
11    also check with the people on the webinar if we  
12    received any questions for our speakers.

13            (A break was taken.)

14            CATHERINE SHEEHAN: All right. Welcome back,  
15    everybody. So if everybody could take their seats,  
16    please. So thank you, everybody.

17            For those of you by webinar, I want to  
18    introduce the next speaker who will present on  
19    interpretation of data obtained from microscopy  
20    measurements. Dr. Taylor Mossman is a distinguished  
21    professor of pathology at the University of Vermont  
22    College of Medicine, going back a few years actually,

1 has over 30 years of research, service, and training in  
2 the field of environmental and occupational lung  
3 disease. She has received a career achievement  
4 recognition award for her scientific accomplishments  
5 from the American Thoracic Society and the Wagner award  
6 from the International Mesothelioma Interest Group for  
7 historic contributions to mesothelioma research.

8 And I did get some information on the  
9 breakouts. The breakouts will be in this room. It  
10 will be partitioned into three, and we will promise  
11 individual easels.

12 BROOKE TAYLOR MOSSMAN: Thank you very much,  
13 Catherine, for that introduction.

14 I am going to talk this morning with one of  
15 the bullet points under this session that Ann Wylie and  
16 I are doing about mineral-type form inventions,  
17 emphasizing on research and others in terms of  
18 carcinogenic facts.

19 So I want to emphasize, in view of all we  
20 heard, that there are many properties of minerals that  
21 have been recognized by geologists and mineralogists  
22 throughout the decades. Most recently, this volume was



1 one that Dr. Gualtieri, a mineralogist, had arranged in  
2 terms of a short course on mineral fibers, again,  
3 emphasizing that there are a number of properties that  
4 are important. This was a short course, and many  
5 individuals in this room played a role in teaching this  
6 course, as well as sampling the volume.

7 I think what's important here -- and I'm not  
8 getting a really good point here though. You probably  
9 can see. I apologize.

10 The point I want to stress is that in the  
11 summary of this pack here, Dr. Gualtieri, myself, and  
12 Dr. Roggli was historically looked at fibers in lungs  
13 in many individuals with disease show that if one looks  
14 at just the mineralogical features of dimension, that's  
15 only encompassed on one of these many boxes which Dr.  
16 Gualtieri has formulated with a number of minerals,  
17 giving them a relative score, in terms of toxicity, and  
18 I invite you to read this volume. I think it's very  
19 illuminating, and there's a wonderful discussion of all  
20 of the other properties other than dimension that are  
21 important in the cancer process. Several of these I'll  
22 touch upon today, but again, there's a myriad of other

1 ones that have become recognized.

2 So I'm going to talk about a tumor that we've  
3 studied for almost 30 years. It's called mesothelioma.  
4 It's associated with exposure to high iron-containing  
5 amphiboles, such as amosite and chrysolite asbestos.  
6 The point I want to emphasize is that the -- and again,  
7 I'm not really getting good feedback on this. But let  
8 me just emphasize that we know that in this type of  
9 tumor that the affected cells are mesothelial cells.  
10 They occur in a contiguous mile layer, which means  
11 they're a single layer that has the property largely of  
12 fluid dynamics in the pleura in the lung cavity and  
13 that tumors arise when long, thin iron-containing  
14 asbestos fibers are able to get out to the pleura, and  
15 I'll illustrate that for you in a minute.

16 So this is what happens, and we'll see if  
17 these animated slides work, but the point I wanted to  
18 make is that the long, narrow amphibole fibers have the  
19 capacity of entering through the, primarily, inhalation  
20 route through the trachea and then a series of  
21 bronchiales that branch into several other smaller  
22 bronchiales until they reach, typically, the end or the

1 air sacs of the lung. And here you see what happens as  
2 they enter. Again, this emphasizes that the rod-like  
3 shape and the dimensions of the amphibole align  
4 themselves with the airways that then penetrate through  
5 the airways through bronchial tubes to the alveoli of  
6 the lung, and you see that here, and then it's  
7 important to realize that they eventually need to get  
8 out to the pleura to cause disease. And this just  
9 shows how these narrow fibers, which because of not  
10 only their rigidity but also some of their flexibility  
11 in working themselves up to the lung, are known to  
12 penetrate through the alveolar sac, and they get out to  
13 the pleura, and then emphasizing that the pleura  
14 consists of two membrane-like structures with this one  
15 pleura and the parietal pleura, and the parietal pleura  
16 is where it's thought that tumors exist in man.

17 It's important to realize that fibers are known  
18 to penetrate through the air sacs, through the visceral  
19 pleura, into the pleural space, and eventually come in  
20 contact with a pliable pleural mesothelioma cells where  
21 tumors exist.

22 It's also been widely studied there are

1 clearance mechanisms that can take these fibers, not  
2 only through cells that are in the alveoli, known as  
3 scavengers or macrophages, but also, lymphatics  
4 naturally penetrate through and between pleural  
5 mesothelial cells and then drain into everything else,  
6 and this is what happens. We all got that?

7           So here you see -- if you look really  
8 carefully, you're going to see fibers, and it's known  
9 that a few fibers can align themselves and be cleared  
10 through lymphatic channel. The problem comes when  
11 there's a high-dose exposure, and you can see what  
12 happens here is a group of long fibers, that the  
13 stomata are occluded, that they build up, and they can  
14 actually come in contact with and persist at the site  
15 of tumor induction over periods of time, as long as 40  
16 years, which is the average latency of these tumors in  
17 man.

18           On the other hand, there's been a lot of work  
19 done with inhalation of short fibers and particles.  
20 It's known that they reach the air sacs of the lung  
21 effectively. They also are removed by stems or cells  
22 called macrophages, completely. And here we see that

1 non-asbestiform fragments are encompassed by  
2 macrophages, and if they are nontoxic, they are  
3 actually taken up effectively. Some of them are  
4 digested. This is known what happens, for example,  
5 with magnesium containing chrysotile is that it breaks  
6 down within these cells; and so these cells can  
7 transport the materials up through the airways; and  
8 other particles, as you see, can go through the somatic  
9 and drain out to the lymphatic system.

10 So the point I want to make is that certainly  
11 dimensions are important in terms of materials getting  
12 to the sites of tumor induction, but there are other  
13 properties that become important in terms of reactions  
14 that are necessary in the carcinogenic process with  
15 mesothelial cells. So our work through the decades has  
16 really focused -- thanks to support from the NIH, EPA,  
17 Mesothelioma Applied Research Foundation, and most  
18 recently, the DOD, we've really focused in our models  
19 today using human mesothelial cells on the properties  
20 of materials that are important in eliciting cancerous  
21 effects; and what we've invariably used in our studies  
22 have been crocidolite asbestos samples. We've used the



1 UICC. We've also used the NIEHS characterized materials  
2 as well, and what we've shown is that crocidolite  
3 asbestos fibers is the prototype, highly pathogenic type  
4 that's been known to cause human mesothelioma, causes a  
5 number of triggering events when it comes into contact  
6 with mesothelioma cells; and this cascade of events then  
7 results in the number of activation of receptors as well  
8 as cascades of a number of critical protein pathways  
9 that give rise to increased cell division; increase  
10 survival, which are hallmarks of cancer; and other  
11 stages that are necessary for a normal cell to become a  
12 full-blown cancer cell.

13 I want to emphasize that oxidants are something  
14 we focused on as being important and that is a result of  
15 crocidolite inhalation as well as interaction with cells  
16 in vitro. We've also focused on, most recently, what  
17 are called epigenetic effects through things such as  
18 microRNAs, which, therefore, affect the DNA to cause  
19 many of these cascades into silence a number of critical  
20 tumor-suppressive chains.

21  
22 So what have we learned about asbestos? And



1 again, I consider myself fortunate in that I've been  
2 able to interact with many of the geologists in this  
3 room in terms of co-authors and supplying me with well-  
4 characterized reference samples; and this is just, as  
5 you know, a general scheme of the classification of  
6 asbestos.

7 Oh, we actually pointed out in the 1990s to  
8 the scientific community that there were actually  
9 different types of asbestos with different packages.  
10 We have focused because of our interest in oxidants and  
11 generation of oxidants as a result of exposure to these  
12 pathogenic types. We hide iron-containing materials,  
13 again, blue crocidolite, and amosite, which Moscow's  
14 studies have reported maybe 20 to 30 percent bulk  
15 asbestos.

16 The other thing I want to emphasize is that  
17 there is little experimental work with, especially in  
18 vitro, with these other types of asbestos that can  
19 contain iron, may not be comparable in terms of charge  
20 but certainly had not been studied with regard to many  
21 of the models that we've examined.

22 So the take-home message here is that through

1 the years we've discovered that the crystallite and  
2 amosite have a number of different mechanisms that --  
3 and I'll go back to this -- that are important in the  
4 persistent release to cells as well as the generation  
5 of oxidants by cells themselves. The important point  
6 here is that the fibers themselves can generate  
7 oxidants by cell-free mechanisms, and they also can  
8 generate what's called frustrated phagocytosis and  
9 generation of oxidants do the uptake by the cells. So  
10 it's been shown that the oxidation state of these  
11 materials is important as well as how the cell  
12 recognizes them, which at low concentrations is curved  
13 by natural production, antioxidants, and high  
14 concentrations. We know that these methods are of  
15 control or healing are curved, and we see cancer-  
16 causing events. All right.

17 Inflammation. Chronic inflammation is also a  
18 feature that we've looked at in our animal experiments  
19 that are important in generation of oxidants. So this  
20 just emphasized the differences that we've noted  
21 through the years, and I'll go into our studies in --  
22 that we've seen, some of the endpoints we've looked at

1 in a few minutes.

2 Here we see what happens. This happens to be  
3 a lung trachea epithelial cell, so this is an event  
4 whereby we use whole 3D X-clamps and corollate these  
5 studies with inhalation work. We've emphasized in our  
6 work that it's the long crocidolite fibers that are  
7 unsuccessfully engulfed by cells who perturb and  
8 produce excess oxidant release, whereas -- what is seen  
9 here by TEM is how effectively short fibers and  
10 fragments are taken up or engulfed by cells. If we --  
11 as these advance over periods of several months in our  
12 models, you see what happens with long, thin fibers.  
13 Here we see -- this is a 3D model, so we see  
14 inflammation. We see accumulation of macrophages along  
15 the fibers. We also see that the fibers act as  
16 matrices for cell division in something called squamous  
17 metaplasia, which is a pre-cancerous step in  
18 development of tumors.

19 So in our experiments, we've looked at a  
20 number of materials. Initially, we emphasized our work  
21 with chrysotile. It's asbestiform, obviously: nature  
22 asbestos, crocidolite asbestos, and amosite asbestos;

1 but we also have gotten from many of our colleagues  
2 non-asbestiform preparations -- in this case,  
3 antigorite and riebeckite that have been supplied --  
4 and we've looked at comparably in many of our models.

5 And this is just a listing of the studies that  
6 we have done where we have prepared various  
7 concentrations of crocidolite asbestos as we -- one  
8 type of asbestos that we really emphasize is the high  
9 iron-containing and oxidant-generating species and  
10 contrasted that with what are called non-asbestos  
11 fragments or preparations of riebeckite.

12 We began in the '80s with preparations of  
13 milled material, or ground material, that we received  
14 from somebody -- might ring a bell to many of you --  
15 Fred Monten (ph), the U.S. Geological Survey. Others  
16 we've received from different sources throughout the  
17 years. The point I'd like to make is that in all of  
18 our studies, unlike a number of laboratories, we've  
19 also done dose responses with all of these materials  
20 and have been unable to detect markers of either  
21 oxidant generation of what are called genes. These are  
22 early responsive genes that are causally related to

1 mesothelioma and the various protein pathways that  
2 we've discovered. These have all been demonstrated  
3 effectively with crocidolite asbestos but not with  
4 riebeckite, and again, our preparations have contained  
5 between about 1 to 6 percent of fibers that are greater  
6 than 5 micron in the riebeckite species that we did  
7 drain them.

8 This emphasizes, again, historically, where  
9 we've proceed with our work. We've looked at cell  
10 survivor proteins. We've looked at cell survival as an  
11 endpoint of -- in growing response to asbestos. We've  
12 looked at cell receptors that simulate many of the  
13 protein pass gates that are important in abnormal  
14 proliferation and survival.

15 In addition to the non-asbestos fragment,  
16 we've applied -- and I'll talk about this more in  
17 detail. We've done studies with the New York State  
18 Gouverneur Mine -- talcs which contain 11 to 59 percent  
19 fibers. Dr. Wylie and Skinner (ph) have been kind  
20 enough to supply us with these materials, and we've  
21 also looked at what's called a Derrick Mine platy talc  
22 in many of our models. In this case, we've looked at



1 mesothelial cells, and we've looked at ovarian  
2 epithelial cells. Have not seen effects of this platy  
3 talc in terms of gene expression, which is time-  
4 dependent and robust with crocidolite asbestos.

5 Curiously enough, in our work with  
6 mesothelioma, these are all human cells -- mesothelial  
7 cells and ovarian epithelial cells. We find ovarian  
8 epithelial cells are very resistant to talc as well as  
9 crocidolite. That's compared to the human mesothelial  
10 cells that are quite sensitive to these materials.

11 So I just want to emphasize the study we did  
12 with Ann in 1997. This I think is important because it  
13 addresses some of the material that I knew you would  
14 hear about today, thanks to previewing some of the  
15 slides by others this morning; but the fact is, in this  
16 study, we looked at both NIEHS samples of crocidolite  
17 and chrysotile asbestos; and we looked at three samples  
18 from New York. Fibrous talcs listed on the previous  
19 slide. We looked at changes that signified either  
20 increases, meaning increased survival of these cells --  
21 again, mesothelial cells and lung epithelial cells. We  
22 also looked at toxicity by looking at the decreases in

1 cell survival of these into colonies, and what we noted  
2 here was that only asbestos caused significant  
3 increases in cell survival, which is one of the markers  
4 that we have looked at in our mesothelial cell systems  
5 and not the fibrous materials, despite the fact that  
6 these materials contained a very high proportion of  
7 talc fibers, of tremolite that is non-asbestiform  
8 tremolite fibers, and also 3 percent in one of the  
9 samples of anthophyllite. And Dr. Wylie, I'm sure, can  
10 comment more on the mineralogy of these materials in  
11 her presentation.

12 So we went on from there to validate our  
13 findings, and what we did is we looked at the  
14 literature on talc exposures, and these are animal  
15 studies. I emphasize here that these studies,  
16 historically, were known as the Stanton Study. Many of  
17 you are familiar with them, I'm sure; but the take-home  
18 message is that regardless of the routes of exposure --  
19 and it's very important that these studies look at  
20 fibrous talc. In fact, in the Stanton and Wrench  
21 studies, they looked at seven different samples, none  
22 of which gave rise to mesotheliomas in their models.

1 Other studies I've listed here because they look  
2 comparatively at asbestos and non-asbestos fragments,  
3 and here, again, are more studies done in different  
4 species using a variety of methods of administration  
5 pointing out that these did not appear to show any  
6 response in terms of cancers developing in animals of  
7 any species with talc.

8 It's also important to realize that there are  
9 a number of additional negative studies. I refer you  
10 to the IARC of 2010. IARC meaning International Agency  
11 for Research on Cancer. Their publications summarize a  
12 number of the studies that I could not add to these  
13 tables.

14 I also want to emphasize that cell studies are  
15 also summarized here, and there have been several  
16 laboratories, including the laboratory by Andrew (ph)  
17 and Catherine and all that have looked at samples of  
18 industrial talcs from Spain, from France, and from  
19 Italy that have not been able to show a significant  
20 increase in any marker of what's called genotoxicity in  
21 vitro in mesothelial cells.

22 So what did we learn through the decades? And

1 curiously enough, this slide came from a National Party  
2 of Science committee that I served on around 1980; and  
3 this was one where Dr. Zoltai and a number of prominent  
4 geologist, Dr. Lanberg (ph), were highly beneficial in  
5 terms of educating biologists on the mineralogy of  
6 asbestos; and in a take-home matter, this probably is  
7 not anything that's new to any of you; but I would like  
8 to emphasize that when one considers a material, one  
9 has to consider more than just dimensions; but we have  
10 to consider what the cell sees or what the lung sees,  
11 and it sees a variety of different crystalline  
12 structures, tensile strengths, chemical compositions,  
13 certainly the surface area, chemistry. The charge of  
14 things such as iron become important, and all of these  
15 have really been related to the endpoint, which is  
16 durability of certain types of asbestos and their  
17 ability to not only get to the pleural but to be  
18 durable there and stimulate changes that occur in  
19 cancer development over periods of as long as 40 years  
20 in some cases.

21 So what we learned about mesothelioma in  
22 humans as well. Naturally, we compare our results to

1 human studies that emerge over time. We know now that  
2 dimensions alone do not explain the ability of a fiber  
3 caused mesothelioma. There, in fact, are many more of  
4 thin fibers that don't cause mesothelioma in them; and  
5 they indeed are different chemically, physically, etc.  
6 And crystallography also varies between these and the  
7 pathogenic types of asbestos fiber, so we have to take  
8 that into account before looking for agents that cause  
9 mesothelioma.

10 And lastly, I just thought I should provide a  
11 few suggestions, apologizing that I'm not a  
12 mineralogist; but I feel that as a biologist I've  
13 interacted with many, and it's really helped me  
14 understand that there are different mineral properties  
15 that may explain the lack of carcinogenicity of non-  
16 asbestiform fragments, such as tremolite, which we've  
17 used in our studies.

18 We also emphasize the importance of dose  
19 response in our work. It's very important if you're  
20 going to assess standards or test materials in biologic  
21 systems that you do dose response of a variety of doses  
22 and concentrations and dose parameters, which we had



1 done in the Wylie work; and this is the only way that I  
2 think you can really sort out what is happening with  
3 these different types of materials.

4 And lastly, I'd like to emphasize that dose  
5 response studies in animals, special inflation studies  
6 are extremely rare. We have done them and shown that,  
7 in fact, there's striking dose responses to chrysotile  
8 and crocidolite asbestos; and low low age (ph)  
9 signatures of cancer are not observed.

10 So I'd like to end here, and we'll move on to  
11 Ann's presentation, which will take these observations  
12 into humans and a little more about dimensions.

13 (Applause)

14 CATHERINE SHEEHAN: So any questions before we  
15 move on and I introduce Dr. Wylie? We have some  
16 questions? Okay.

17 GREGORY MEEKER: Well, it's a comment more  
18 than a question. But amongst the materials that I  
19 collected for NIOSH, there is a range of rather  
20 asbestiform tremolites that vary in iron content from  
21 non-detectable up to around 10 percent; and I think  
22 that will be a really useful reference set to examine

1 beyond hypothesis further, and I'm just leaving it out  
2 there that those materials are prepared NIOSH.

3 BROOKE TAYLOR MOSSMAN: Yeah. I meant to talk  
4 to you about that, and I know we did briefly before the  
5 meeting; but I think that your presentation here really  
6 has illuminated sources of materials that can be well -  
7 - that are well characterized that can be examined by  
8 laboratories, and I really appreciate that  
9 presentation.

10 MATT SANCHEZ: And, obviously, a lot of these  
11 are commercial properties, which are very happy to  
12 measure as a great one too. But surface area is one  
13 that's been talked about. Philip Cook (ph) spent a  
14 fair amount of time with it. I think it should also be  
15 looked at with greater vigor.

16 Also, I wanted to ask you a bit. As you were  
17 looking at inflammation pathway, how important was that  
18 inflammation pathway as a precursor to the carcinogenic  
19 outcomes or those physiologic changes; and have you  
20 looked at, also, the fibrogenics outcome as well?

21 BROOKE TAYLOR MOSSMAN: Yes. That's the  
22 finding from NIEHS and your National Heart, Lung, and

1 Blood Institute. We have looked at great numbers of  
2 asbestosis and have models of asbestosis by inhalation.  
3 The difficulty, as you know, is mesotheliomas take the  
4 lifespan of an animal to develop, and we have not been  
5 able to do those. We go out several months, and we  
6 look for early indicators of mesothelial self-  
7 proliferation.

8 Your point is really a very good one in terms  
9 of these standpoints. Surface area you brought up, and  
10 I think that is something that Ann and I looked at. We  
11 actually -- now, I think I've moved the scientific  
12 community to -- rather than just adding weights of  
13 materials to models, that they actually adjust for  
14 comparable surface areas; and you actually get a whole  
15 lot of differences between fiber types much easier if  
16 you can do comparative surface area on determinations.

17 MATT SANCHEZ: Thanks.

18 AUDIENCE MEMBER 1: Have you looked at the  
19 Canadian chrysotile and into the Globe, Arizona  
20 chrysotile? Because that's essentially pure white.

21 BROOKE TAYLOR MOSSMAN: Right. I haven't.  
22 The only chrysotile that we looked at in Canada was the

1 UICC reference sample, and when we started these  
2 experiments, we used -- UICC was the Canadian and  
3 Rhodesian, and we also did crocidolite. Then with the  
4 characterization in the NIDHS samples that were  
5 characterized by Ann in the camalital (ph) paper, we  
6 were able to get enough to do inhalation experiments  
7 and dose response studies. So I think --

8 AUDIENCE MEMBER 1: There was a test of the  
9 iron, and the gold stuff is so clean, they used it as a  
10 blood filter in World War II for pongee (ph), and of  
11 course, every soldier in the Pacific who was wounded  
12 liked the old Arizona chrysotile.

13 BROOKE TAYLOR MOSSMAN: Yeah. I wasn't aware  
14 of that, but I think -- I was somewhat disillusioned  
15 before coming to this meeting because the NIH of  
16 samples no longer exists; and the fact that we can now  
17 get samples from NIOSH and different institutions -- we  
18 miss samples -- really is going to be very helpful.

19 AUDIENCE MEMBER 2: Did you look at short  
20 chrysotile too?

21 BROOKE TAYLOR MOSSMAN: Yes. We had sized  
22 materials, and we didn't see any effects. We were

1 looking, again, at endpoints of self-proliferation. We  
2 did not do inhalation studies with the short.

3 Yes.

4 AUDIENCE MEMBER 3: The type of particles that  
5 got in through the mesothelial layer in your studies,  
6 as you indicate, some of them bound to the surface in  
7 some were able to penetrate the cell. Was there a  
8 difference in size or composition between those  
9 different types of fibers?

10 BROOKE TAYLOR MOSSMAN: Yes. There was a  
11 difference in size. As Bob referred to, we gave our  
12 size materials -- chrysotile. We also had different  
13 size fiberglass. Preparations of size definitely was  
14 an important feature in terms of cell uptake. However,  
15 the iron content and the fact that the block made the  
16 changes that we saw with antioxidants indicated the  
17 importance of chemistry -- iron charged, iron surface  
18 availability, for example.

19 AUDIENCE MEMBER 3: Thank you.

20 CATHERINE SHEEHAN: Okay. So briefly  
21 introduce Dr. Wylie. Currently a professor in the  
22 Department of Geology, University of Maryland, College



1 Park. She holds a BA in geology from Wellesley College  
2 and a PhD in economic geology with minor concentrations  
3 in mineralogy and petrology, structural mineralogy, and  
4 mining engineering from Columbia University; and she  
5 joined the faculty of the University of Maryland in  
6 1972 where she taught courses and directed research in  
7 geology.

8 So I'm going to set your presentation up.

9 ANN WYLIE: Okay. Thank you very much. It's  
10 a pleasure to be here, and thank JIFSAN for inviting me  
11 and Nora for all her hard work.

12 I have my name -- only have my name up there  
13 because it's sort of an opinion piece, but I wanted to  
14 recognize that I have work on (inaudible) Chrisantha  
15 (ph). I'm working with Allen Seagreg (ph), and some of  
16 the data we have, I will copy that; and some of the  
17 work toward the end this fall has benefited from  
18 conversations with Andrew Corechefski (ph), Andrew  
19 Duane from Chemistry and Industrial Hygiene, and Mark  
20 Loutel (ph) from the University of Rochester; and we  
21 are working together on some of the things that I'll  
22 talk about today.

1           So the question we have is amphibole. I'm  
2       just going to speak about it generally. Is it  
3       asbestos? You know, sometimes that question is very  
4       easy to answer. Depends on the size of the particle.  
5       It can be very easy to answer. It also can be somewhat  
6       confusion -- confusing and not so clear on a particle-  
7       by-particle basis, and I always deal in populations for  
8       that reason.

9           Is it hazardous? I think that's the basic  
10      question. Not so much how it formed in the absolute,  
11      but is the material hazardous? What does the lung see,  
12      as some people have mentioned? And how do we identify  
13      it? And by that I mean something that might be  
14      hazardous, and when you have to -- when you're dealing  
15      with cosmetic or pharmaceutical talc, which is really  
16      the topic here, then we really do need to know how do  
17      we identify it.

18           Now, today I'm really going to talk only about  
19      amphiboles. I'm not going to talk about anything else  
20      because that's really, I think, the issue that we have  
21      here before us. And this is almost the identical slide  
22      that Brooke ended with, so I can skip over it very

1 quickly. But we do know that there are certainly more  
2 than dimensions. I don't want to assume that that's  
3 the only thing. There are many things that impact bio  
4 durability, but I'm just going to talk about dimensions  
5 and the dimensions of sets of data that are composed of  
6 elongated mineral particles; and by that, I mean 3 to 1  
7 particles. So I'm only going to talk about elongated  
8 mineral particles. I use the term EMP for that purpose  
9 just to describe the data set. And at the end of the  
10 talk, I'll come back to the issue of fibrous talc.

11 I believe it's a good place to look at -- the  
12 effect of dimensions in amphiboles because we haven't  
13 seen a lot of variability in terms of their retention  
14 characteristics other than dimensions in the lung or  
15 their solubility or many of the other issues that might  
16 impact their clearance or -- and so as a group, they're  
17 pretty insoluble and have a lot of characteristics in  
18 common, so we can try to isolate dimensions.

19 Well, if you knew my children, you would know  
20 that -- they'd tell you that I never throw anything  
21 away; and so when I was being asked to come and talk  
22 about amphibole and talc, I literally went into my

1 bathroom closet, and I found a bottle -- this is the  
2 god's truth -- I found a bottle of baby powder, and so  
3 I brought it to my office, and I made mounds, and I  
4 looked at it under the microscope. And sure enough,  
5 voila, I found tremolite, and I had no problem finding  
6 it. I mount tremolite in an index of refraction oil,  
7 1.578. That makes talc effectively invisible because  
8 it's a metal in the index of refraction, and so a quick  
9 scan of a large number of particles will show you  
10 immediately where you have high index material like  
11 amphibole. You can see talc platelets on end. They  
12 also stand out because they have a very low index, but  
13 this is a very easy distinction to make.

14 And I think our basic disagreement about  
15 things and why we're here is that: Do we accept the  
16 counting criteria that are used to assess the magnitude  
17 of exposure to asbestos in environments where asbestos  
18 is known to occur? We developed a whole methodology  
19 for protecting worker and for making sure buildings  
20 were clear when we knew asbestos was there. Do we  
21 accept those as the definition for asbestos? And  
22 that's the crux of the problem.

1           This is not asbestos. This is just a piece of  
2   rock. I mean, you look at it under cross-colors you  
3   see that it is a fairly uniform material. It's not  
4   composed of fiber bundles. It's not asbestos. It  
5   can't even be inhaled. This is 19 by 83 micrometers.  
6   You can't inhale it. It's not going to braid up when  
7   you put the powder on your body to make a lot of other  
8   little particles out of it. So this is not -- to me  
9   this is not asbestos, and I don't think I'm gonna get a  
10  lot of disagreement about that from anyone in the room.

11           If it's not asbestos and it meets the 3 to 1  
12  and longer than five, then how do we approach the  
13  problem? How does FDA approach this problem? I think  
14  that's the crux of the matter here. We need a  
15  different definitional characteristic for tremolite if  
16  we are going to enable the identification of asbestos  
17  or hazardous particles in talc.

18           I'm hoping this next slide shows up. I've got  
19  a new camera, and I'm not so sure. It's okay. Now,  
20  this is a sample of tremolite asbestos. Art Langer, you  
21  gave this to me, gosh, a zillion years ago. It comes  
22  from Metsovo, Greece, where there's a high



1 incidence of mesothelioma and other lung diseases among  
2 the residents of four villages in Greece. Art reported  
3 on it, and it's tremolite, and it's asbestos; and it's  
4 about the same size particle, about 11 micrometers wide  
5 and 77 micrometers long. And there's no question that  
6 this is asbestos, and even if this is just a -- not as  
7 nice as those electron microscopy pictures, when you  
8 look at it under the cross-colors, you can see that  
9 it's composed of lots and lots of little fibrils, and  
10 they break up easily just like spaghetti and have all  
11 the characteristics that make asbestos, in my mind,  
12 dangerous.

13 But can we tell these forms apart? And I will  
14 grab, there are many variations between this and the  
15 one I showed you before in terms of habit but not in  
16 terms of relative abundances. Almost all the amphibole  
17 that makes up the crust of the earth and in the United  
18 States -- I would say that's between 6 and 10 percent  
19 of all rock is made of amphibole. Almost all of that  
20 is just ordinary garden-variety material that will form  
21 cleavage fragments if you break it up. That's just --  
22 it's not uncommon, but it is uncommon -- it is rare in

1 terms of its abundance, and any of the other forms are  
2 there also. You can find them. There's nothing out  
3 there you can't find, I have learned, but I'll keep  
4 going.

5 So I want to talk about dimensions. I want to  
6 talk a little bit about width and length. Where are we  
7 going here? So as Brooke I think has well summarized,  
8 those particles that are known to cause asbestos-  
9 related diseases, where we actually have it in human  
10 populations. We have narrow widths on long fibers. It  
11 is the narrow width that makes asbestos flexible. You  
12 can actually bend any rock if you can make it long and  
13 thin enough. That's the truth of the matter. So it's  
14 the relative proportion -- the flex, the width -- that  
15 gives flexibility and people are so tired. I wrote a  
16 whole paper on this, this great mineralogist that was  
17 mentioned earlier.

18 Width and density control the aerodynamic  
19 behavior of fibers. Width controls the penetration  
20 potential of fibers deep into the lung and access to  
21 the pleura, and migration through fluid vessels in the  
22 body is controlled primarily by breadth; and when I say

1 very narrow, I'm talking about fiber rates that range  
2 from less than .4. I'd say around .35 to .03, which  
3 are about the narrowest fibers that I've seen reported  
4 in the literature.

5 Now, length -- again, we look at length and we  
6 know that, as Brooke described very clearly, the short  
7 fibers are removed by a variety of mechanisms. The  
8 long fibers persist, and almost everyone that has  
9 studied the issue believes that long fibers are more  
10 important in the carcinogenic response than short.  
11 We find abundant long fibers in lumber and stumps. The  
12 long fibers appear to be preferentially retained in the  
13 lungs. The short fibers are removed, and of course,  
14 ultimately, for the work I'm going to talk about a  
15 little bit later, it's important that our occupational  
16 exposure, our risk analysis, all the things that we  
17 depend upon to understand the carcinogenicity of  
18 mineral fibers are based on exposures to long fibers --  
19 L5. I call them "L5." I got tired of saying "length  
20 greater." So L5 fibers, that means longer than five.

21 And the -- there is, however, a conundrum that  
22 we face, and that word was used before. I hope I'm

1 using it properly. Whereas, the long fibers are  
2 associated with disease, the short fibers are much more  
3 abundant. The mobile fiber lengths for crocidolite,  
4 that 1 to 3 micrometers; amosite, 1 to 5; Libby 1 to 4;  
5 and so forth. So there's lots and lots and lots of  
6 short fibers, but I'm gonna focus on the long ones for  
7 all these reasons that I described. I do treat the  
8 widths characteristics of long and short fibers  
9 differently for that reason.

10 So in the court cases that are in front of us,  
11 the Davis set's been entered in evidence. It's part of  
12 the public record. I took it, and I plotted it, so I  
13 wanted to see from my own mind what is it exactly that  
14 we're talking about in talc.

15 And so these are L5 elongated mineral parts.  
16 They meet 3 to 1. They're longer than five, and they  
17 were -- the data was provided by Longo (ph) in 2017;  
18 and what we see here is for these long fibers. You see  
19 that there's a range in fiber widths. It's actually  
20 fairly uniformly divided between .2 is the narrowest  
21 fiber recorded. There are no .1 fibers in that data  
22 set, and they range the -- I put the mode on there --

1 it's hardly a mode, but at least it's the highest value  
2 -- at .4, but they stand rather regularly over to about  
3 1.2 micrometer, and then there's another bump out there  
4 at 1.5. Now, I want you to remember the shape of this  
5 curve because I'm gonna come back to it a little bit  
6 later.

7 I know that Metsovo, Greece tremolite asbestos  
8 that I showed you, this is the width distribution. I  
9 thank you Allen (ph) for these data, and you can see  
10 that the mobile width is .175, and this is a very  
11 uniform material. It's remarkably uniform. It has  
12 virtually no fibers braids, and that's .4. S little  
13 tiny bit out there. There's always going to be those  
14 things. It's very, very narrow, and it doesn't look at  
15 all like that other sample, and I want to show you  
16 putting them side by side on the same scales just what  
17 I mean when I say they don't appear to be the same at  
18 all. And so this material has a wide long range and  
19 low abundance of a lot of different material. This  
20 material has a very narrow range and a very high  
21 abundance -- a small number of widths.

22 So we have what we know about asbestos as a

1 human carcinogen. Comes from exposure to asbestos in  
2 human population, in mine population, industrial  
3 workers of all sorts; but I want to look then -- let's  
4 look at -- compare what I just showed you to what we  
5 actually know about what asbestos is like. And I like  
6 this slide very much because these data come from Shedd  
7 in 1985, the Bureau Mines. She measured  
8 extraordinarily carefully. You had very high  
9 magnification. A lot of different crocidolite samples,  
10 and the one on the left shows you that there are molds  
11 of crocidolite that are very, very tiny -- .03 in width  
12 and the one from the Cape there is about .05. You  
13 know, mostly, you don't know that that's there because  
14 the way we do measurements -- a part of the  
15 measurements is we use wide bins when we plot  
16 frequency. So this and that, those are exactly the  
17 same data. There's no difference in those two data  
18 whatsoever. It's just that this is plotted at a very,  
19 very narrow bin width, and I wish that we had data like  
20 this on amosite. I wish we had it on a lot of things  
21 because they -- biological potencies of those very,  
22 very narrow fibers, it's like it was rather poorly



1 investigated.

2           So this -- most of the width distributions  
3 that I can show you have bin widths of about .1  
4 micrometers, and so you'll see. If that's there, I  
5 don't know. We'll see what I'm going to show. It's  
6 like this, but I do want to point out that virtually  
7 every fiber in these samples is less than .4  
8 micrometers in width and the abundance of particles is  
9 the greatest, less than .1.

10           Now, it's also very important for us to  
11 remember that just because we call something  
12 crocidolite or tremolite asbestos or whatever, that  
13 does not tell you much about it because mineral samples  
14 are location specific. There's no ideal one of any of  
15 these things, and these are four different locations  
16 where crocidolite asbestos is mined; and the first two,  
17 again, these are single individual samples, are from  
18 the trans -- I'm sorry -- from the Cape and from  
19 Australia, and they have the very narrowest widths,  
20 .05. And then when you move into the Transvaal, you  
21 can see that the width -- the modo (ph) width is much  
22 wider. It's still pretty narrow but much wider. And

1 then when you got to Bolivia, which they are still  
2 mining crocidolite down there, by the way, you see a  
3 much different kind of distribution.

4 In 1971 there was an article published in  
5 Nature and -- by Timbrell, Grifferson (ph), Pooley,  
6 1971 who -- the title of the article was The Role of  
7 Fiber Width in Mesothelioma, and at that time they were  
8 looking at mesothelioma among the mine populations in  
9 the world, and they didn't find any in the Transvaal.  
10 Now, the Transvaal doesn't just mine crocidolite. The  
11 major asbestos mine there is amosite, and these widths  
12 are a little bit wider than this. But for the Cape and  
13 Hamersley that the widths were much wider, and they  
14 postulated that it is the width of the fibers in South  
15 Africa -- these two locations -- that explain this huge  
16 abundance of mesothelioma in the Cape and its lack in  
17 the Transvaal. I think they had one case. Somebody  
18 might be able to tell me another. Reference that for  
19 prep.

20 And then I'm gonna look again at comparing. I  
21 just picked one of these asbestos populations from  
22 Hamersley, Australia. Again, this is the Shedd data,

1 and this is data from our lab, and this is the  
2 California riebeckite. And I want you to look at the  
3 shape of the distribution, a large number of evenly  
4 abundant particle sizes and width, a little bit --  
5 another big bump out here a little bit further. This  
6 is exactly the profile of those tremolite particles  
7 that Belongo (ph) presented as coming from a platy  
8 talc.

9 So let's look at some of the other types of  
10 asbestos that we know have a potential to cause  
11 asbestos-related disease. This one was characterized,  
12 again, by my lab by SEM. I think -- I wish I had done  
13 the TEM, but I was young and stupid; and here you can  
14 see that we have a mode at about .33, and then there's  
15 a shoulder on this width. They may be two independent  
16 sets of data there, two modes that are just not clearly  
17 defined. There's certainly a couple more as we go out.

18 Amosite has very fine fadders. I see a .1.  
19 Just about 6 or 7 percent in this particular profile,  
20 and at .2, there's 15 or 16. So there's a lot of  
21 narrow fiber. There's a lot of white fiber. Amosite  
22 is very interesting. Mineralogical studies have shown

1 that there is actually -- there are -- other than  
2 amphibole minerals that sometimes form between the  
3 fibers that tend to glue them together, and there is a  
4 structural continuity across fibers; and so I think  
5 amosite doesn't break apart quite so readily, but it  
6 does indeed have these very, very narrow fibers that  
7 are characteristic of asbestos.

8 Libby. Okay. So mesothelioma is known from a  
9 Libby and these data were gathered by MRI in a study  
10 that was done a long time ago. They were extracted  
11 from the ore, and you see a pattern; and by the way,  
12 this pattern looks exactly the same as the pattern of  
13 the amphibole in the air around the town of Libby that  
14 was collected by EPA not all that long ago. So this is  
15 a very stable cross-section, here, frequency diagram.  
16 I'm not -- I have numbers of fibrous elements exactly  
17 the same. So this is at .34. We have -- we have  
18 another bi-modal distribution. Like this beginning to  
19 show an amosite, but we can clearly see it here, and  
20 then it will kind of lump out further.

21 This second may be a courser fiber. It may be  
22 two different periods of fiber growth that have

1 produced this. It could have broken fragments in  
2 there. I'm not totally sure what it is, but that --  
3 this profile is very characteristic.

4 And we've talked about Italy. So the  
5 epithelia, there's mesothelioma among the people who  
6 worked in the quarries there. These are data from  
7 Paoletti (ph) and Bruny. They published their data in  
8 charts, and I copied it, so I'm not totally -- well, I  
9 think my arrow copy is .02. So I think these are  
10 pretty good representations of what they show, and  
11 again, you see kind of the same sort of thing. You see  
12 a lot of very narrow fiber -- .25. You see a secondary  
13 peak at .5 and another one at .75 and then one a little  
14 bit further down.

15 And finally, this is Pokela , Finland.  
16 Asbestos was mined there for, I don't know, hundreds of  
17 years, and it stopped production in the year of 1970s.  
18 At that time there was no -- and even into the '90s  
19 there were no mesotheliomas at all reported from  
20 Pokela. The population there has a -- the recent  
21 publication where there are some mesotheliomas  
22 reported. I don't know what that means since it's



1     been, you know, 40 years since the mine closed; but  
2     nonetheless, I'm not sure about the mesothelioma  
3     potential for this particular anthophyllite, but I  
4     would predict that it should, based on this. You can  
5     see it's got very narrow fiber in it. It has this bi-  
6     modal distribution, and there's a lot of characteristics  
7     that are similar to the ones that we have seen.

8             So if I were to summarize, what does the width  
9     look like in asbestos, I would say that we have one  
10    type, which is like crocidolite and that Metsovo  
11    tremolite asbestos where we have 50 to 60 percent of the  
12    fibers that are longer than 5 micrometers. Now, I'm  
13    only talking about longer than 5 micrometers and the  
14    percentages are all those particles that start out at  
15    least at 3 to 1. 50 to 60 percent are less than .2, and  
16    amosite and -- we have the dimensions of crocidolite  
17    present, but generally speaking, the width is a bit  
18    larger.

19            We move onto Libby and to Pokela and Italy, we  
20    see these bi-modal distributions. We see the presence  
21    of these very narrow fibers, in decreasing proportions  
22



1 perhaps, but they do all have particles of width less  
2 than .2. So if I'm looking for asbestos, I'm gonna  
3 find out -- I'm gonna look for what's always there.  
4 It's always less than .2. It's always there, and so if  
5 you're gonna call something asbestos, you better have  
6 particles in there that are longer than 5 and less than  
7 .2.

8 Now, does all this matter? Does it make any  
9 difference whether these particle populations are  
10 different? Does it matter? And the only way we know  
11 is to look at the patterns of disease among the mining  
12 population and mesothelioma mortality. Most of our  
13 studies are done from mixed exposures, you know, where  
14 you have four different kinds of asbestos or an unknown  
15 exposure to asbestos -- workers and that sort of thing.  
16 But there are estimates of mesothelioma potency, and  
17 the measure which I'm just referring to, they often  
18 refer to as RMeso, and that's the percent of all  
19 expected deaths per fiber -- per fiber, and that's by -  
20 - per fiber. I'm talking about the ones that are  
21 measured for occupational exposure, longer than 5 and 3  
22 to 1 expectation, so the sack per fiber, per cc, per

1 year. So that's the measure, and Hodgson and Darnton  
2 published some mineral-specific values for RMeso, and  
3 Garrett and Castillo (ph) have updated these data. The  
4 Journal of Toxicology and Applied Pharmacology has a  
5 volume coming out very shortly -- I'd say within the  
6 next three weeks -- from a conference that was held on  
7 this topic in Virginia a year ago, and this paper is in  
8 that volume. So it's something certainly to look for.  
9 A lot of them are -- papers are already available  
10 online.

11 And so they published an update on crocidolite  
12 and amosite. They added the Libby and the mining  
13 populations at Homestake, South Dakota; and Homestake  
14 is the largest and oldest active gold mine (inaudible).  
15 It's a great place to go to. I like (inaudible), but I  
16 like it anymore. But the miners there mine deep  
17 underground mines in a rock that's basically made of  
18 grunerite and quarts. And so they were exposed to  
19 these particles, and we do know that there is -- has  
20 been no asbestos related diseases in that population.

21 I think there will be additional studies come  
22 available that we can use. And what do I mean by

1 "being able to use?" Exposures to a single mineral.  
2 And what do they show, and I'll show you some real  
3 data, but I just want to be sure that the point is  
4 clear. They show that for the same occupational  
5 exposure as measured in fiber per cc year that there is  
6 a great difference in mesothelioma mortalism from  
7 location to location, minerals content, and that must  
8 be reflected one of these or more characteristics. It  
9 has to reflect dimension or durability, composition,  
10 and common structure. It should have been right there.  
11 It should reflect something that's different from  
12 location to location.

13 So here are the data. These are from Garrett  
14 (ph), Brad (ph), and Custor (ph). Asbestos type and  
15 location. Now, there's a lot of assumptions should  
16 come into some of the data that I'm gonna show you, but  
17 these just come right out of the paper. You can read  
18 it yourself, and I'm giving you the RMeso for overall  
19 crocidolite, and that's from the Cape and Transvaal.  
20 So for those two locations the overall -- and they  
21 published one for the Cape, and they published one for  
22 Hamersley and they -- you know, they have several; but

1 I averaged these, and they have averaged them, so I'm  
2 giving you the average. It's 0.451 and that's the --  
3 95 percent confidence intervals are shown there.

4 Amosite in the Transvaal, look how far that  
5 drops. It drops way down, 0.09. Winchite and  
6 Richterite asbestos from the vermiculite workers of  
7 Libby, Montana, 0.028. Drops down. Overall chrysotile  
8 0.0012. I'm going to talk about that, and we're about  
9 to be perplexed with some of the things that Brooke  
10 talked about. It's a different mineral. We usually  
11 can't compare them.

12 And then fragmented grunerite from Homestake  
13 gold mine in Lead, South Dakota. This is not asbestos  
14 and there is no excess disease, so they have RMeso at  
15 zero.

16 So what do we do with those data? Well, we  
17 need an index for the toxicity of durable mineral  
18 fibers. What index can we use that we can compare and  
19 try to understand this mineral difference? And I got  
20 three up here. There might be a lot of other ones.  
21 Litman (ph) has suggested that in order for minerals to  
22 produce mesothelioma it has to have a width less than

1 about 0.15. Stanton used 8 micrometers and 0.25 in  
2 width, and I dreamed up another one here. Longer than  
3 7 and a width less than 0.4, and I have -- I'm using  
4 that one. I'm gonna show you some data from that one  
5 because Fred Pooley, in his studies of lung tissue and  
6 what particles actually get to the pleura, has shown --  
7 and this paper's coming out in this volume --that these  
8 7 micrometer particles long are sitting right there at  
9 the surface of the lung waiting to move into the pleura.  
10 And Lance (ph) et al. published their assessment that  
11 particles have to be less than 0.4 micrometers to make  
12 it to the pleura. Now, we can argue about those. I'm  
13 not sure these are the right, but I've got three here,  
14 so let's look and see how they work. It could be added  
15 that I hope our work, as we go forward, will improve  
16 this.

17 So what we have plotted here is the total  
18 fiber in the exposure and what proportion of that fiber  
19 meets certain width definitional criteria. So let's  
20 just take this first gray triangle there. That is for  
21 length greater than 7, width less than 0.4. That's for  
22 crocidolite, and I've averaged crocidolite at eight

1 populations, so I'm happy to -- it's a way to gain  
2 (inaudible). Anyway, there it is. So it's 58 percent  
3 of the crocidolite fiber fall in that category. For  
4 amosite, it's about 30 percent. For winchite,  
5 richterite asbestos from Libby, it's at 17 or 18; and  
6 for Homestake, it's zero. But that is with a simple  
7 regression line on there, and put it just right through  
8 all those, and so that quotes the percent expected  
9 deaths against a dimensional characteristic of a  
10 population; and I did that for the length greater than  
11 7, width less than 4. I did it for width less than  
12 0.15. I did it for length greater than 8, width less  
13 than 0.25.

14 So in the fiber per year, this tells you  
15 something about what that fiber that they were  
16 breathing in actually looks like. It isn't a bunch of  
17 particles that are 5 micrometers long and 1 micrometer  
18 wide. There are much different from that, and they  
19 vary among these native sacks, which I think is a --  
20 the reason why the mesothelioma potential varies. The  
21 0.85 and the 0.15, they almost fall on exactly a  
22 straight line. They are very, very similar. The R



1 squares should be something like 98 percent, and they  
2 put these when you only have a points. You only need  
3 two to get 100 percent now. (Audience laughs.)

4 So let's try -- can we use this to predict?  
5 Can we take a curve like this and predict mesothelioma  
6 outcome? So I've taken three samples I'm gonna show  
7 you. One is in Metsovo, Greece, where we know there's  
8 mesothelioma. One is Pokela, where we're not so sure,  
9 but if my medical (inaudible) would see, what would  
10 they predict. And then I've taken the data from Italy.  
11 What does it predict in terms of -- at home, I don't  
12 know how to plot error and square in the Excel. I'm  
13 old and really backward about all that, so I asked a  
14 friend of mine to do that for me. I have all the  
15 errors. I just want to show you what the errors are in  
16 these points. So these are one standard deviation in  
17 the percental fiber and 95 percent confidence interval.  
18 Just want to be sure. We talk about error earlier.

19 All right. So here are these three curves,  
20 and Metsovo, Greece tremolite plots on these three  
21 different curves, and it plots at an average of about  
22 0.3 RMeso, so you know, something in there. By all

1 these criteria it should cause mesothelioma. Of  
2 course, we know it does. With young Lidia (ph), in  
3 Italy, well, that one is around 0.2 expect for the  
4 width less than 0.15, and it's way down here in the  
5 lower corner. There were no data from that chart I  
6 copied of particles that were less than 0.1 micrometers  
7 in width, so I'm not 100 percent sure about the quality  
8 of that data point. And then Pokela, Finland, they  
9 plot at about the same level as well. Just a little  
10 less than 0.1.

11 Okay. So how do we use all that information  
12 to help the FDA? That's the question. This, again, is  
13 from Metsova; and under PLM, do I have any trouble  
14 telling this from that? I don't think so. I don't  
15 think anybody would have any problem. This is composed  
16 with a zillion fibers that are less than 0.2  
17 micrometers in width. I mean, it is a material that  
18 will come apart. If this were in talc and you rubbed  
19 it on your body, I'm not sure you wouldn't release a  
20 lot of this fiber. You might start with a certain  
21 number. You might end up with a lot more. I think  
22 when you inhale fiber particles that it's aggravating

1 your lung. So I think there's a lot to be said for the  
2 health effects of asbestos because of the habit that it  
3 forms, and it certainly is predicted by my analysis  
4 that this would be highly carcinogenic. No problem --  
5 this is a PLM. This particle is 18 micrometers wide.  
6 It didn't come out from a talc deposit. Here's another  
7 particle from that bottle -- my children's baby powder  
8 -- and it's not asbestos. It isn't a fiber bundle. It  
9 can't disaggregate. It can't be inhaled. Nothing can  
10 happen to this that I know of that has any health  
11 hazards associate with it whatsoever, none. And  
12 there's no confusion about a particle this size, about  
13 whether or not it's asbestos, using PLM. By PLM, it is  
14 unambiguous.

15 AUDIENCE MEMBER 1: Did you throw out the  
16 bottle?

17 ANN WYLIE: Pardon?

18 AUDIENCE MEMBER 1: Did you throw out the  
19 bottle or keep using it?

20 ANN WYLIE: Well, it's -- my children are in  
21 their 40s.

22 Okay. So the analysis issues in cosmetic talc

1 I think are the crux of the matter. And we ask: Is  
2 the amphibole in talc -- is it asbestos? Does the talc  
3 contain chrysotile? And how do you distinguish  
4 anthophyllite from fibrous talc? So let me just make a  
5 few comments on these things.

6 Okay. You see amphibole asbestiform. Well,  
7 the talc that I looked at under my microscope last week  
8 or week before -- week before Thanksgiving, actually --  
9 the particles were huge. I mean, we're talking about  
10 70 micrometers. Wow, these are huge. And these talc  
11 particles were gigantic. I don't know what I was  
12 expecting. Why we would have gone to the TEM, I'm not  
13 totally sure. Almost everything that I saw in this  
14 bottle was very, very large; and so polarized light  
15 microscopy is great for this kind of thing. You can  
16 see fiber bundles no problem, and they're going to be  
17 there -- I contend that if it's amphibole and it's  
18 really asbestos, they're going to be present in these  
19 large sized particles. They don't just all break up by  
20 themselves. The talc does. Remember talc is the  
21 softest mineral known. If it's not breaking up into  
22 tiny little particles, I don't know why the tremolite

1 would. But if we go to the electron microscope and we  
2 count 3 to 1 long, width 5, what about -- how do we  
3 deal with that? How do we look at those data? And I  
4 think you have to ask at those data whether or not  
5 you've got particles that have widths less than 0.15.  
6 Do you have lots of particles that are longer than 8  
7 and less than 0.25? Do you have a lot of particles  
8 that are longer than 7, less than 0.4? I mean, are  
9 these particles that are asbestos-like present in the  
10 sample? If it's chrysotile -- well, I would ask: If  
11 there's serpentine found in talc, is chrysotile evident  
12 by light microscopy? Chrysotile asbestos is just like  
13 amphibole asbestos in the sense that when it occurs as  
14 asbestos in veins, it seems you should be able to see  
15 this no problem. If it's dispersed -- if it's like a  
16 mass fiber deposit, sort of mass fiber -- chrysotile  
17 plus talc, you'd have to go with the TEM, but I don't  
18 know of any assurances like that. Now, some of the  
19 rest of you may. I just am unaware of that occurrence.

20 I found this in that same bottle of powder  
21 that -- I swear it was there. And this is fibrous  
22 talc, and I know it's fibrous talc because the indices

1 of refraction are too low for it to be amphibole.  
2 They're not even close. It also has an extraordinarily  
3 high birefringence. In other words, the indices of  
4 refraction parallel and perpendicular to this bundle  
5 are vastly different and the material shows up under  
6 polarized light microscopy without a problem. It is  
7 actually so simple under a PLM to tell fibrous talc  
8 from anthophyllite asbestos.

9 Let me just -- so let's talk about some of  
10 these issues because I see this issue all the time.  
11 People talk to me about this. Why is it a problem? It  
12 appears to me that by chemistry and morphology that the  
13 grains of fibrous talc and anthophyllite asbestos look  
14 an awful lot alike by SEM (inaudible) 1:14:55.1; and  
15 they look very, very different by optical, and the  
16 reason for that is that optical microscopy is sensitive  
17 to the water content. Water content lowers the  
18 density. When you lower the density, the indices of  
19 refraction go down. But TEM and SEM are insensitive to  
20 the water, and so people confuse them all the time by  
21 just looking at chemistry. As I've said before you can  
22 easily tell these two apart.



1 Now, I've talked to a number of TEM  
2 microscopists and asked, "Why do you have this problem  
3 all the time of fibrous talc being called anthophyllite  
4 asbestos?" And they said that in ISO, methodologists  
5 that -- not always when you have two minerals in that  
6 similar composition that are constantly present, not  
7 only do you look at the zone access pads for  
8 consistency, whether it's tremolite or anthophyllite,  
9 but you also want to evaluate them for inconsistency  
10 with the crystal structure of other minerals of similar  
11 composition and this is simply not done. It is not  
12 evaluated. It used to be that -- just the 5.3.  
13 Instant spacing got the definition of anthophyllite,  
14 and then we started getting a few zone access patterns,  
15 but they are not necessarily specific for  
16 anthophyllite. They may be consistent, but they may  
17 also be consistent with talc and, therefore, do not  
18 provide the necessary distinction. I know this can be  
19 done, but I think it is an extremely difficult  
20 proposition. And those of you who deal with electron  
21 microscopy can comments on that in a little bit more  
22 widely.

1 Well, I was asked weight percent versus  
2 particle number. Boy, there's a really different way  
3 of looking at things. I don't think you should begin  
4 an analysis for asbestos unless you know it's there. I  
5 just don't think so, and you can tell that it's there  
6 by looking for evidence with fiber bundles, scanning  
7 the slides by PLM. You have some indication that you  
8 have asbestos present by mechanisms that we know are  
9 reliable before you began counting individual  
10 particles.

11 Normally the levels are very low in tremolite,  
12 in top material; and that is a consistency -- there's a  
13 possibility of then homogeneo (ph); and we had a little  
14 earlier discussion. Someone said they looked at  
15 20,000, and there wasn't any; and then someone else did  
16 some concentration, which is a very good way to abuse  
17 PLM, by the way. I think it could be sample  
18 inhomogeneity at those very low levels. But PLM, you  
19 can -- particularly if you concentrate, you can get as  
20 low of a sensitivity as you want. It just depends on  
21 how much material you want. Really? And how much time  
22 you want to spend. But 0.1 or .01 percent BLM is

1 pretty easy.

2 Remember, the mass is in the large particles.  
3 It's not in those little tiny particles. They don't  
4 have any of the mass. It's in the big particles. We  
5 have particles that are 100 micrometers wide, and we  
6 are trying to measure the mass of a component with the  
7 little particles that are 1 micrometer? The mass is in  
8 the big stuff.

9 Now, fiber number, that is a very complicated  
10 approach. I don't think that it is helpful in terms of  
11 estimated percentages of anything. I don't -- I think  
12 there's a great deal of difficulty and reproducibility.  
13 I'm going to leave it to the TEM people to comment on  
14 this. What are you going to count? What do you  
15 measure? If you use TEM or SEM and you measure fiber  
16 number, I would argue that you must record the length  
17 and the width of every particle that you measure so  
18 that you can evaluate the population for toxicity, and  
19 that would be the recommendations that I would have to  
20 give you. Thank you.

21 (Applause)

22 CATHERINE SHEEHAN: Thank you very much.

1 ANN WYLIE: You're welcome.

2 CATHERINE SHEEHAN: So any questions? We got  
3 questions?

4 AUDIENCE MEMBER 4: Yes. Often when we're  
5 looking at talcs that have these amphiboles in them,  
6 what we're seeing aren't necessarily singular  
7 structures. We often see bundles, and it's difficult  
8 to actually determine what we're going to use for the  
9 width in a bundle if you have a bundle that has, say,  
10 some fibers that are 0.3 and some fibers that are  
11 particles within that bundle that are less than half a  
12 micron. How would you address that when you said you  
13 should be measuring the aspect ratio of every particle  
14 by EM?

15 ANN WYLIE: All right. I never measure aspect  
16 ratio. Aspect ratio is an absolutely useless  
17 parameter. It's dimensionless. It has no value.

18 AUDIENCE MEMBER 4: Wake me up.

19 ANN WYLIE: So I really -- I feel really  
20 strong about that. Well, when you look at all of these  
21 distributions, we all had that problem. We have it in  
22 every distribution that's ever been done, but in terms

1 of particle -- you just take the width. Just take the  
2 width. Whatever it is, take the width. Of the bundle,  
3 whatever, take the width; but you should have --  
4 asbestos easily disaggregates by hand pressures. It's  
5 one of the definitions. It easily disaggregates, but  
6 you're gonna have a lot of the other things in there,  
7 and I wouldn't worry about that one bundle. I would  
8 worry more and measure more those individual particles  
9 that you see which are by far more abundant than the  
10 one particle that you're talking about. That's been my  
11 experience.

12 AUDIENCE MEMBER 4: Well, my question was,  
13 basically, if a bundle is defined as three or more  
14 fibers, parallel each other, separated by less than the  
15 width of one fiber and those individual fibers have  
16 different widths, how do you determine a width of a  
17 particle when you said that ever particle must be  
18 measured for its length and width?

19 ANN WYLIE: I would measure the bundle, as I  
20 told you. I mean, all those populations that I've  
21 shown you -- all right. There is thousands and  
22 thousands and thousands of measurements, and whenever

1     there was a bundle, we measured the width of the  
2     bundle. All right? Because the number of those  
3     particles that are individual far out -- exceed -- and  
4     that's why you always have tails. That's why you  
5     always have tails on distributions of asbestos. You  
6     don't always just -- it doesn't just end at .1 or .2  
7     micrometers. It's all -- the crocidolite decided it's  
8     so readily that you tend to have much shorter tail on  
9     crocidolite. All right? For me, I (inaudible) why  
10    it's so dangerous because I think it would disaggregate  
11    under any circumstances, but the -- you measure  
12    whatever you see there, and then -- that's what all of  
13    these are based on. We never try to say, well, what  
14    about those individuals that make that thing up? Never  
15    tried to do that. So all the data that I'm showing you  
16    here, it's just every particle however it presents --  
17    bundle, no bundle -- are what makes these data. That's  
18    what I've showed you, or that's how we've dealt with  
19    it.

20           AUDIENCE MEMBER 5: Just a comment, actually.  
21    Showing up. If you can't do magnification better and  
22    better and you keep chasing zeros, you can end up



1 increasing the number of fibrils or fibril masses gone  
2 to the individual fibril. Now you've got millions  
3 where you only saw one bundle to begin with. The end  
4 is sitting right here. Just measure what's there, not  
5 the individual separations.

6 ANN WYLIE: Yeah. Next question.

7 GREGORY MEEKER: I appreciate what you said at  
8 the end about measuring individual by TPM the  
9 dimensions, and then you went on and said something I  
10 think was wrong.

11 You said because then you can calculate from  
12 that the toxicity, and I guess you were getting it in  
13 mass, and mass is really irrelevant in toxicity. It's  
14 the number of individual small fibers that are gonna  
15 reach the lung. Because as you said earlier, 70 micro-  
16 like fiber never going to reach the lung, but it --

17 ANN WYLIE: Right.

18 GREGORY MEEKER: -- has a huge mass. It's  
19 gonna overwhelm millions of other fibers.

20 ANN WYLIE: That's right.

21 GREGORY MEEKER: As Roe (ph) said 40 years  
22 ago, .25 percent in talc, it still had billions of

1 fibers.

2 ANN WYLIE: No. I agree with you. I don't  
3 disagree with anything that you said, and I think that  
4 you misinterpreted. If you're gonna measure particles,  
5 you're not going to be calculating mass. I mean, that  
6 would be fiber number, and that's where I think you  
7 measure everything; and I think it's a very complicated  
8 to extrapolate from TEM print to an entire ball of  
9 talc. But nonetheless, I think what you're measuring,  
10 measure everything; and then what I met my toxicity, I  
11 think that you have to have asbestos-size particles to  
12 have asbestos-related disease. Now, that's my opinion,  
13 but -- so I would say that if you don't have  
14 populations of particles that have widths less than  
15 0.4, then -- and I mean 0.35 measured or less --  
16 usually there's a 0.05 error -- then it's very unlikely  
17 that you're going to have the kind of toxicity that we  
18 see with amphibole -- of crocidolite. Now, that --  
19 that's my opinion, and you know, it's not something --  
20 and I say it is that based on some of the work that I  
21 just showed you why I think that way, because I didn't  
22 get to see dose response on those sized particles.

1 AUDIENCE MEMBER 6: I wanted to put in a good  
2 word for aspect ratios. (Audience laughs.) One of the  
3 biggest that we found useful with aspect ratios is that  
4 as you look up populations of non-asbestos fibers and  
5 asbestos fibers, the diameter of the asbestos fibers,  
6 the width stays pretty narrow. So as they get longer,  
7 the aspect ratio jumps up, and it doesn't happen with  
8 non-asbestos fibers. If they get longer, they get  
9 fatter, so their aspect ratio goes flat.

10 ANN WYLIE: My experience has been exactly the  
11 opposite. The longer they are, the higher the aspect  
12 ratio concluded fibers, and I've got a lot of data  
13 published that shows that.

14 AUDIENCE MEMBER 6: Compared with asbestos?

15 ANN WYLIE: No.

16 AUDIENCE MEMBER 6: That's the comparison I'm  
17 making.

18 ANN WYLIE: No. As you -- if you take  
19 ordinary tremolite and crush it off, when you look at  
20 the smaller particles, the aspect ratios will be last,  
21 and it isn't until they get longer does the aspect  
22 ratio increase. So I don't like aspect ratio, because

1 when we see populations and you compare two populations  
2 up here on aspect ratio, you do not know what the range  
3 of length over which those particle populations  
4 represent. And so one of them might represent  
5 particles from 2 to 100, and one might represent  
6 particles from 1 to 20; and that might be very, very  
7 different; and we're not comparing apples and apples in  
8 that way. Aspect ratio can be very misleading.

9 AUDIENCE MEMBER 6: We were building the size  
10 distribution and then we're comparing the aspect ratios  
11 of the two populations, so you know what the lengths  
12 are.

13 ANN WYLIE: As long as you compare aspect  
14 ratio over the same length range, then I think it has  
15 some validity for comparative purposes; but if you  
16 don't have the same length range, then you are not  
17 comparing apples and apples.

18 AUDIENCE MEMBER 6: I agree.

19 AUDIENCE MEMBER 7: I've got one question  
20 along these lines. Has it been determined if someone  
21 said reason or bundle, what happens over time to the  
22 bundle in the lung? Did they -- are they -- do they

1       come in a case like at Cenegenics? Are they individual  
2       fibers? Does anybody know?

3               ANN WYLIE: Well, maybe, Brooke, you can  
4       answer. Most of the data I've seen shows single  
5       fibers.

6               BROOKE TAYLOR MOSSMAN: Yeah. I think a lot  
7       of the original work on the fiber breakdown in bundles  
8       was done by Bob (ph) a long time ago, in the 1960s; and  
9       he did show that even long asbestos fibers in  
10       Crocidolite-enticed talc broke in.

11              AUDIENCE MEMBER 7: Okay.

12              ANN WYLIE: There was a wonderful study by  
13       Coffen (ph) on, apparently, actinolite in rats, and  
14       they -- I think they did inflation. I'm pretty sure.  
15       And then they killed the rat slowly over a long time,  
16       and looked at the populations; and with time, the  
17       numbers of fibers in the lungs increased. And that  
18       shows you that those bundles were breaking up. So I'm  
19       pretty sure that that's my answer.

20              AUDIENCE MEMBER 7: Uh-hum.

21              CATHERINE SHEEHAN: Hunthro (ph).

22              AUDIENCE MEMBER 8: I've had, I guess, a

1 unique opportunity with my association with Dr. Dodson  
2 to have analyzed postal valves and lung tissue samples,  
3 and it was interest. Your width is, I think, spot-on  
4 is what I see; and I can show you data because we have  
5 compiled length and width. Where I would take  
6 objection is the greater than five. The vast majority  
7 of fibers that I find are actually not less than 0.4  
8 but probably less than 0.25.

9 ANN WYLIE: In width?

10 AUDIENCE MEMBER 8: In width. And less than 5  
11 in length.

12 ANN WYLIE: Yeah, I know. That is the  
13 conundrum about length, and I don't understand that;  
14 and every population I have ever seen or looked at has  
15 the most abundant fiber tests in 5 micrometers or less.  
16 So there's no question about that, and that is a  
17 problem, a conundrum is something I don't exactly know  
18 how to deal with; and I know how Dr. Dodson feels, that  
19 this is important; and particularly, I think it's going  
20 to be important today; it will be important in  
21 inflammation; it will be important in asbestosis; maybe  
22 it will be important in lung disease; but for



1 mesothelioma, I'm not so sure.

2 AUDIENCE MEMBER 8: I could hear him in my  
3 head. (Audience laughs.) The question he's asking is:  
4 How long does it have to be in there to start the  
5 process?

6 ANN WYLIE: That's a good question. I just  
7 use five because all our exposure data is five, and if  
8 I'm gonna use data that suggests the variability of  
9 your potential to get disease, I have to use it on the  
10 basis of fiber, measure, and exposure.

11 AUDIENCE MEMBER 8: Exactly. That's just on  
12 the occupational exposure is all five. So we don't  
13 have that data --

14 ANN WYLIE: Right.

15 AUDIENCE MEMBER 8: -- to be able to -- you  
16 know, the data that I've been able to find shows that,  
17 yeah, the majority of the population is less; and it  
18 matches very closely what we find -- what I've been  
19 finding in human lung tissue.

20 CATHERINE SHEEHAN: Okay. We're cutting into  
21 our lunchtime now, so we can take one more question. I  
22 see two hands up. Okay, Aubrey (ph).

1 AUDIENCE MEMBER 9: Yes. I thought your  
2 analysis was really interesting trying to look at the  
3 differing sizes and shapes related to mesothelioma, and  
4 obviously, at the beginning of that exploration into  
5 the arenite populations and other populations --

6 ANN WYLIE: Yeah.

7 AUDIENCE MEMBER 9: -- as well; and obviously,  
8 the worker populations are selective, so I think that  
9 would be commercial asbestos.

10 Have you also been trying to look at other  
11 health influences as well? Lung cancer, fibrogenic,  
12 interstitial lung disease, fibrogenic pleural lung  
13 disease because they -- there's different sensitivity  
14 to different size and shape with respect to the other  
15 health influences, and they're just as important as  
16 mesothelioma.

17 ANN WYLIE: Oh, the anthophyllite workers in  
18 Pokela margin -- the population was full of asbestosis  
19 and lung cancer. And so there's no question in my mind  
20 it's -- the certain area of anthophyllite is very high.  
21 Timbrell did work on surface area and demonstrate very  
22 clear to my satisfaction that he can explain asbestosis

1 on the basis of the high surface area of anthophyllite.

2 So, yes, I absolutely --

3 AUDIENCE MEMBER 8: We actually do those same  
4 kind of analysis.

5 ANN WYLIE: Absolutely. Now lung cancer is  
6 very hard because the data that have been shown by  
7 Garret, Brad, (ph) and Castillo (ph), and Hodgson and  
8 Darnton show no correlation, no variability that I can  
9 call against dimensions. So I don't know. Lung cancer  
10 I don't understand. There's a lot of factors there,  
11 and it's not just a dimensional argument.

12 AUDIENCE MEMBER 9: You know, stop and shield  
13 or --

14 ANN WYLIE: Yeah. Yeah. No. You know, I  
15 don't.

16 CATHERINE SHEEHAN: Okay. I hate to break  
17 this up, but we have to move on. So lunch is from 1:30  
18 to -- I'm sorry -- 12:30 to 1:30. I see they're  
19 setting up the buffet outside, but most importantly,  
20 the breakout sessions are going to convene in this room  
21 divided into three. Recall that you signed up for two  
22 of three sessions, so come back and be prepared to know

1 which of the sessions you have signed up for or we will  
2 have chaos.

3 The co-moderators for Session A on tech methods  
4 is now Robyn Ray and Frank Ehrenfeld. The Session B,  
5 measurement criteria, the moderators are Ann Wylie and  
6 Art Langer; and then the third session on interpretation  
7 of testing data is Brooke and Matt Sanchez. So  
8 everybody knows where to go after lunch.

9

10 (A lunch break was taken.)

11 CATHERINE SHEEHAN: So what we're gonna do now  
12 is if everybody can come back into the main room. We  
13 are going to begin with a report-out by session  
14 moderators. The report-out will last for 45 minutes,  
15 and so we'll do the math. Here, we have three  
16 sessions, so we have to stick to our 15-minute time.

17 So I will begin with Session A, if I could  
18 have Frank and Robyn. If they can come up and share  
19 their report-out.

20 When we're done with the three report-outs for  
21 Sessions A, B, and C, we will then go into a discussion  
22 questions for the moderators; and that will last half

1 an hour, 30 minutes. So we should be out of here --  
2 basically, we should be done by five o'clock; but I  
3 will finish off 15 minutes with closing remarks and  
4 next steps. So --

5 FRANK EHRENFELD: Can we have ten minutes to  
6 put our ideas together here?

7 CATHERINE SHEEHAN: Okay. Do you want to go  
8 second? Which of the sessions -- A, B, or C? Who  
9 wants to go first?

10 FRANK EHRENFELD: We're just putting our notes  
11 together.

12 CATHERINE SHEEHAN: You're putting your notes  
13 together.

14 FRANK EHRENFELD: I thought we had more time.

15 CATHERINE SHEEHAN: Yeah, I was given the  
16 instructions to get this thing moving, so if you're not  
17 done, we don't have any choice.

18 FRANK EHRENFELD: Okay. Here we go.

19 CATHERINE SHEEHAN: You're good?

20 (Background chatter)

21 FRANK EHRENFELD: We seem to be down a few  
22 people. Do you want me to get some more people back in



1 the room once you --

2 AUDIENCE MEMBER 10: I'll grab them.

3 FRANK EHRENFELD: We'll do that.

4 (Background chatter)

5 Okay. Folks, I think we're ready to go here.

6 I want to summarize for our Session A today. Session  
7 A, this is our charge is before you on the screen.  
8 Martin added his. And so we were charged with what  
9 test method for the analysis of talc and mineral fibers  
10 in cosmetics -- it was very specific -- where asbestos  
11 is not there and the word "cosmetics" are there. So we  
12 sort of specified that as we went through this.

13 And, again, here we are again. I will tell  
14 you that we had a lot of assistance putting these notes  
15 together, this presentation, from Robyn Ray who is the  
16 special projects manager for asbestos for EMSL; and  
17 again, I'm Frank Ehrenfeld. I'm the laboratory  
18 director at IATL in New Jersey as well as the chair of  
19 ASTM D2207.

20 We started by asking for a show of hands as to  
21 who our audience was, and so we discovered that we did  
22 have a number of geologists. We had a number of lab



1 rats that specialize in various traditional  
2 technologies and techniques. We had XRD represented  
3 several times over, a number of light microscopists and  
4 electron microscopists present. We had those who were  
5 familiar with some of the medical epidemiological  
6 background of the subject as well as a toxicologist in  
7 the room. Everybody should have a toxicologist in the  
8 room when they're meeting. We also had those who were  
9 involved in the regulatory community.

10 We had a number of things that we wanted to  
11 consider, including about the matrix of the material.  
12 Some matrix considerations were discussed. We can even  
13 look at an overview of that.

14 Is this something that is a talc deposit, and  
15 what analytical methods might be appropriate for that  
16 versus what analytical methods and techniques would be  
17 appropriate for talc in a product? Obviously, our  
18 charge was cosmetic, so a product.

19 We talked about some of the products  
20 themselves, to what extent would they be used. Was it  
21 something that was bound in waxy matrix like lipstick  
22 or something that, perhaps, was more materially that

1 could be readily airborne like a talc?

2 We also talked about the lack of reference  
3 standards and calibration standards. We talked about  
4 all of these various analytical techniques in detail.  
5 One of our core conclusions was that no one analytical  
6 method shall trump another and that you must have  
7 either complimentary or a suite of analytical methods  
8 in order to be able to confirm these minerals in those  
9 matrices.

10 Under the term "other," we actually had a  
11 couple other things proposed for -- to overcome certain  
12 challenges, including SEM OSHA analysis using EDS --  
13 thank you, Greg, for taking me back to my days as a  
14 graduate student at Lehigh -- as well as ICP mass spec  
15 to look at some of the chemistry of the minerals as well  
16 as the matrices.

17 Under "prep options," we were reminded by Chris  
18 Weis, our toxicologist. Careful about prepping your  
19 sample. Do not create anything if you can get away with  
20 it, and don't diminish or demolish or dilute anything  
21 that might already be in there. So careful not altering  
22 the material as it is received for

1 a laboratory -- in the laboratory.

2 We have other takeaways regarding prep  
3 options. We talked about various modernization  
4 techniques. We talked about the disadvantages of  
5 knowing -- and everything you see here on the slide, we  
6 talked about it at least in some length.

7 We also talked a great deal about, okay, once  
8 it's under a light microscope or in the XRD or under  
9 the SEM or TEM, to what extent are you going to -- I  
10 don't want to use the word "limit" an analysis but to  
11 extent -- or to tolerate some limit, to put it in  
12 Martin's terms. But we thought that the best idea was  
13 to analyze everything so the microscopist would never  
14 have to put that sample back into a stove and if  
15 there's a particle there that can be analyzed and the  
16 dimensions recorded and the chemistry measured and the  
17 fraction pattern obtained and documented, that you do  
18 it right there and then. Don't have to go back and do  
19 it.

20 One of the other filters that we mentioned a  
21 couple different times had to do with an unknown or a  
22 certain tie it up here. We also asked repeatedly about

1 those who had experience analyzing these materials, and  
2 a number of hands went up as well. So the room had a  
3 lot of experience in it.

4 What we said we would learn some of the  
5 lessons from the morning sessions, and I proposed that  
6 we filter our comments through these couple points that  
7 were made by Greg Meeker -- two of these points -- Ann  
8 Wylie, Martin Harper, while in the hallway, and others.

9 Greg said, "Is it possible to protect public  
10 health without regulating everything?" So we had to  
11 think about that, to what extent. You know, where's  
12 your cost-benefit analysis? If you're doing an  
13 analysis of material, do you want to analyze  
14 everything? Do you want to have that boxcar of an ore  
15 deposit pull up and somebody say, "Okay. Tell me what  
16 this has or does not have in it" or, "Here's a thimble  
17 full of material. We need your analysis to proclaim  
18 the asbestos or mineral fiber content of this boxcar of  
19 material"? So all that stuff we considered. So to  
20 what extent is public health going to be protected  
21 without regulating everything?

22 Another comment that filtered our



1 conversations had to do with geologists used to own the  
2 definition of asbestos, and it has been -- and those  
3 definitions have now been turned over, for better or  
4 worse, to the legal community.

5 Greg had another important statement that we  
6 used to filter our discussion, which is: "What does  
7 the lung know?" So regardless of how you might define  
8 a particle or a fiber, what does your lung have to say  
9 about it?

10 Make sure I have all of these out of the way.  
11 We were also concerned about it turning into a  
12 discussion about asbestos definitions, and we at some  
13 point there was at least some murmur of consensus about  
14 the fact that the initial definitions of "asbestos" had  
15 to do with materials that were intentionally formulated  
16 with these minerals for building materials and other  
17 such things and if there are other products that might  
18 be contaminated with these minerals or coming up out of  
19 the ground that they may not -- that we need to maybe  
20 create another definition for them. Those are some of  
21 the filters.

22 Again, the main points to take away from our

1 discussion, use multiple techniques and technologies.  
2 Make sure that your prep is sound and not either  
3 removing anything that you might detect or creating  
4 something that you're going to be counting. And also,  
5 if you're gonna analyze something, take the time and  
6 analyze everything so that 20 years from now they can  
7 use that data and not have to reinvent the wheel.

8 And again, we had a lot of minor points that  
9 will eventually come into a summation that we'll submit  
10 to JIFSAN.

11 And any questions before I'm done with your  
12 little synopsis there? Yes sir.

13 AUDIENCE MEMBER 1: Did you discuss a possible  
14 combination of these techniques, whether these or some  
15 of the others that you mentioned, that could be used as  
16 an additional screening process that could --  
17 identifying risk, maybe be a way of identifying talc  
18 that was reasonably safe and should be making in our  
19 commerce, you know, based upon, you know, what our IHHE  
20 or one of the risk assessments we come up, give us some  
21 number to hit on; but what I'm looking for here is a  
22 screening protocol that might be a little over



1 sensitive, but if it gave false positives, bam, then  
2 you go ahead and do the additional confirmatory  
3 analysis to get rid of it.

4 But what I'm looking for is an initial  
5 screening protocol that would give us, you know, a high  
6 -- relatively high confidence that whatever product got  
7 through was safe for the public.

8 FRANK EHRENFELD: Okay. That's a long  
9 question. Let's see if I can get it down to its bare  
10 components there. The last thing was like, hey, with  
11 this screening protocol, can I have a high confidence?  
12 But that may be counterintuitive there -- screening and  
13 high confidence, right? However, we did bring up at  
14 least the term that: Now, what would you use first? Is  
15 there an order you'd use these analytical techniques?  
16 Is one better than the other? Can you just go straight  
17 to this analytical method? And the answer over and over  
18 again was, "No. You need to use a suite or use multiple  
19 confirmatory techniques."

20 Nobody was too confident with using a  
21 screening method outside of using light microscopy at  
22 least on the ore deposit side of things, only cosmetic

1 products -- finished product side of things. Obviously  
2 there would have to be a lot of prep involved, and  
3 then, again, you're losing some of the pool --

4 AUDIENCE MEMBER 1: That's a whole -- that's a  
5 whole different.

6 FRANK EHRENFELD: Yep. I may not have answered  
7 your question, but at least some of those elements were  
8 discussed. Again, most of the comments that we shared  
9 also related to the morning sessions.

10 Sean.

11 AUDIENCE MEMBER 2: We discussed XRD and PLM  
12 as valid screening pools that have advantages and  
13 disadvantages, but I thought we had agreed a group that  
14 some form of electron microscopy was needed for final --  
15 or at least quality assurance.

16 FRANK EHRENFELD: Yeah. And with that, we  
17 also discussed measuring the width of various suspect  
18 minerals, and so TEM would obviously need to be used  
19 for that, with the limitations of light microscopy, in  
20 order to collect the data that might have pertinent  
21 biological information. TEM would have to be used.

22 Any other questions? Okay. Thank you very

1 much.

2 (Applause)

3 Of course the secret weapon of our session was  
4 Art Langer, so we had a wonderful broad-ranging  
5 conversation about all sorts of things.

6 Our goal was to establish concurrence on a  
7 morphological criteria for the identification of  
8 mineral fibers in cosmetics containing talc, and so the  
9 things that I think we did agree on was that the longer  
10 than 5, aspect ratio 3 to 1 gives you -- may give you  
11 false positives. All right. So although it will patch  
12 her what we're interested in, in an analysis, it would  
13 necessarily -- or likely give you false positives if  
14 both fragments and asbestos was present.

15 We also noted that 3 micrometers is the limit  
16 of respiration for fibers, and so that's an important  
17 limit on what should be included if respiration is the  
18 method of entry.

19 Someone asked if you could get talc through  
20 the skin. I don't think we were experts enough to  
21 answer that, but I think it was raised. We then agreed  
22 that particle morphology using this standard method for

1 assessing asbestos exposure will exaggerate, or may  
2 exaggerate, asbestos fiber counts.

3 We agreed that the analysis should look at and  
4 focus on particles longer than 5 micrometers, and we do  
5 not accept coal without dissent, that it's only long  
6 particles that we should be worried about; but what  
7 we're looking for is an index and an indication that we  
8 have fiber present. And since all of our risk  
9 assessment and everything that we know about how these  
10 minerals were likely to behave are based on that, that  
11 analysis should focus on longer than 5 micrometer  
12 particles.

13 We also believe that the FDA has an  
14 opportunity for a method of analysis of a bulk  
15 material, that there is no reason to apply a method  
16 that was used for air sampling and environments known  
17 to contain asbestos to bulk analysis, that that leak is  
18 not necessarily warranted; and we urge the FDA to think  
19 creatively about what else they could do to try to  
20 develop a method in bulk -- criteria for bulk  
21 materials.

22 We agreed that false positives by just simply



1 conventional counting can be enhanced by using more  
2 than one type of instrumentation. Polarized light  
3 microscopy is an advantage over phase contrast, that  
4 electron microscopy gives us another set of data by  
5 which we can make the analysis; and so I think we concur  
6 with what was discussed earlier. These -- the analysis  
7 would benefit significantly in bulk materials by heavy  
8 liquid separation, that we should use it. We use light  
9 microscopy. It should be polarized light microscopy.

10 We agree that we need -- if we're using  
11 electron microscopy, we need to establish a set of data,  
12 a certain number enough to feel that a mode has been  
13 established in width. So we measure a large enough  
14 population in order to establish a width mode so that  
15 that can be compared to known asbestos populations to  
16 enhance the certainty of the definition -- of the  
17 identification.

18 We had, I thought one, a very interesting  
19 discussion. It was a little bit outside our direct  
20 charge, but the question would be: At what level can we  
21 tolerate a mineral fiber in talc?

22

1           And I think Martin had a really good idea to  
2       use some of the risk assessments that have been done at  
3       Libby. We know exactly what Libby looks like. There's  
4       enough information in that analysis that they establish  
5       a safe level and that that might be used to help  
6       establish a tolerable limit for analysis, and an  
7       analyst has to have a detection limit. They have to  
8       have a level below which you can't prove the absents,  
9       and so we need something. We need some limit that we  
10      work toward in the analytical community no matter what  
11      criteria that we apply.

12           Anything else? Anybody from our group, again?

13      Okay.

14           (Applause)

15           MATT SANCHEZ: All right. I'll tell you  
16      excuse my computer up here. It's limited space, so I  
17      took my notes on here.

18           I would like to excuse Brooke Mossman. I'm  
19      pitching when you can go to her as a co-moderator of  
20      one of the sessions, and then Brooke Mossman had to  
21      leave to catch a plane, so I'm -- I don't know. I'm  
22      just pitching and gone. (Audience laughs.)



1           The goal that we are given, which I learned  
2   about two days ago, was to establish a consensus on the  
3   interpretation of microscopy measurements for mineral  
4   fibers in cosmetics containing talc. I would --  
5   fellows kind of liked my show. There was a lot of give  
6   and take with the participants. I'll do my best to  
7   summarize kind of what I thought I said and then also  
8   based upon some of the questions for those that were in  
9   the other panel -- or in that one meeting.

10           Before I do that, I would just recommend, if  
11   you haven't yet, there have been two stimuli articles  
12   published by the USP, the different expert panels  
13   working on testing talc for asbestos. I think it was -  
14   - the discussions in both of those are very relevant to  
15   everything we've discussed today, and it also gives an  
16   idea of the talc expert panel, which is working on  
17   analytical methods, the direction we're going. There's  
18   some information about where we're going with that, and  
19   we'll be more forthcoming, too, in the coming year I'm  
20   sure.

21           One thing that I noticed from the morning  
22   sessions is nobody defined a mineral. I found that

1 interesting because in any of the interpretation of  
2 microscopy data, or any analytical data dealing with  
3 minerals, you need to make sure that you've collected  
4 enough data to identify them. So this is a basic  
5 working definition of the mineral. This is where you  
6 get "a natural occurring solvent." It's going to have  
7 a crystal structure. It's crystal in it. It's gonna  
8 have a chemical composition. You can measure something  
9 that's consistent. So depending on however you're  
10 looking at the sample, whatever kind of technique  
11 you're using, be it XRD -- XRD's not going to tell you  
12 anything about the composition of what you're looking  
13 at. It will tell you what crystal and phases are  
14 present. When you're looking at PLM, PLM's not going  
15 to tell you anything about the composition directly.  
16 Based upon refractive indices in the amphibole, you can  
17 make some inferences.

18           There was a lot of -- you know, Ann rightly  
19 pointed out that anthophyllite and thallophyte, PLM,  
20 that's child's play to tell those apart by refractive  
21 index. However, I mean, you move into things like  
22 tremolite and anthophyllite, if they're not

1 asbestiform, you're dealing with an extinction-angle  
2 difference. You can tell them apart by the distinction  
3 angle, otherwise you can't.

4 When you're dealing with a phase like  
5 cummingtonite and actinolite, you're never going to  
6 tell those apart only by optical data. So if these  
7 specific mineral species of interest are important, the  
8 optical data could get you pretty far; but if you're --  
9 you may be assuming something incorrect if you just  
10 call it actinolite. There could be something else.  
11 And I will say that in historical talcum powders that  
12 I've been testing over the past year, we are finding  
13 cummingtonites that historically were reported as  
14 actinolites and tremolites. So that is a -- from a  
15 historical perspective, that is something that is real.

16 And so just moving on, when you're -- so when  
17 you're evaluating data, it's critical to understand  
18 what these instruments can and can't do on  
19 identification. I spoke -- I'm trying to think it  
20 here. So sorry. I'm gonna follow my notes.

21 One of these -- we were pushing for in the USP  
22 expert panel -- maybe I'm speaking for them, but what



1 I'm trying to push for is the data that's reported with  
2 any test report would contain all the information  
3 necessary for third parties to be able to independently  
4 verify the results. What that means is, if it's the  
5 PLM testing, there will be photographs of the particles  
6 and plane-polarized light in different directions with  
7 the -- so you can see the Becke` lines or dispersion  
8 stain colors, however you're doing that, where you have  
9 imagines showing what the extinction angle if one was  
10 observed was, when you have imagines to see what it  
11 looked like, you know, signing and longation, all these  
12 different measurements. I require that those things  
13 all be reported because through all those pieces of  
14 information that an analysis is supposed to be doing,  
15 you can then understand what the data actually means  
16 and whether there's been misinterpretation on the  
17 laboratory side.

18 The same holds for any kind of a TEM analysis.  
19 The different issues with TEM make it much more  
20 difficult. They're not more difficult. I know it was  
21 said earlier that somehow PLM is not sophisticated, or  
22 it seemed to be implied that, and that's just not true.

1 Minerals are very complicated. The technology and the  
2 science and the physics behind polarized light  
3 microscopy are also very complicated. They're very  
4 robust within their limitations.

5 The same goes for TEM. TEM has very wonderful  
6 things that it can do. Martin Rutstein mentioned this  
7 idea of this 5.38 row spacing by, you know, TEM  
8 analysis to somehow confirm an amphibole. Talc has  
9 that. Sepio has that. There's a -- any bio pyro glass  
10 (ph) -- that's a new term for everybody -- will have  
11 those 5.38 in row spaces. That does not make them  
12 amphiboles. That does not make them asbestos.

13 So whenever these issues are coming up in TEM  
14 data, the SAED data that's collected must be robust  
15 enough that you have zone axis to fraction work -- and  
16 this is all spelled out in old documents from the EPA.  
17 This is also spelled out very precisely and good by the  
18 ISO Methods by using TEM, but when you need that zone-  
19 axis work -- and then the zone-axis solution needs to  
20 be specific to the mineral you're identifying. There  
21 are a lot of zone axes for different minerals that will  
22 be the same, so unless you have a unique solution, you

1 cannot say you've identified that mineral. A caution -  
2 - a cautionary note, that most -- I can't speak -- in  
3 my experience, I'll leave it at that, a lot of asbestos  
4 testing labs by TEM only have crystal structures  
5 provided to them through NVLAP which does not include  
6 the crystal structure of talc. So how is the lab  
7 supposed to analyze talc for asbestos if they can't  
8 differentiate by electronic fraction talc and  
9 anthophyllite? I'll just leave it at that.

10 There was a lot of comments from the audience  
11 there. The questions, a lot of them revolved around  
12 almost like surrogate techniques to measure for  
13 asbestos content or amphibole content. One of the  
14 discussions revolved around using, you know, calcium as  
15 a tracer for maybe a tremolitic or at least a calcic  
16 amphibole. I did my best to try to deal with those  
17 issues. You know, talk about using iron. There's just  
18 issues if you're trying to do a certain chemical  
19 solution for these things, and I hope I explain this  
20 well enough that that was clear. I think we're stuck  
21 with doing microscopy on individual particles for the  
22 most part.



1           Some of the discussion dealt with the  
2           quantification revolving trying to do techniques to  
3           concentrate, like, amphibole phases from talc, which  
4           can be done in a variety of ways. There's pros and  
5           cons to doing that, but I tried my best to discuss what  
6           those are; and really, I think from an idea of getting  
7           better quantitation, I think there's a lot of merit to  
8           doing concentration techniques once you've identified  
9           whether something is there to know how much is there.

10           But you know, for an example, if you take 10  
11           milligrams of talc, put it in a heavy liquid separation  
12           and, you know, do your thing and then look at the  
13           residues, that's the same as just looking at that 10  
14           milligrams of talc but actually by PLM, which you can  
15           do rapidly and quickly. So there -- but from a  
16           quantitation perspective, to be able to remove the  
17           nonamphibole from those components, you can get a much  
18           higher idea of the quantitation, get a much lower --  
19           much more sensitive burden. Accurate quantification is  
20           best by using those kind of techniques at the expense  
21           of, you know, doing nothing about chrysotile, if it is  
22           present or not.

1           There was a lot of talk about the idea --  
2       especially from the FDA groups, there was an idea of,  
3       you know, having a rapid and also reliable testing and  
4       screening of these materials. My recommendation was  
5       for rapid testing, I think PLM is the best. We can do  
6       it on site if you were equipped to do it, but again, I  
7       agree with what was said earlier. I think doing  
8       multiple approaches is necessary here. There's a lot  
9       of -- a lot of nuances, and having other techniques,  
10      they complement each other. Where you have  
11      contradictions in the data, you need to resolve those  
12      contradictions, and a lot of times other techniques  
13      will be able to allow you to do that.

14           There was also some discussion of the  
15      cosmetics, and I think Frank Ehrenfeld already mentioned  
16      that -- the idea of removing, you know, waxes or binders  
17      from them. The amp flows are there. I think that would  
18      have to be done before you analyze reliably. Those  
19      things could mask and make it difficult to measure  
20      pertinent properties of those particles for  
21      identification.

22           I think I -- I think that was all my notes I

1 had. I don't know if anybody that was in the group had  
2 anything to add. Did I miss anything important?

3 AUDIENCE MEMBER 3: Ross (ph)?

4 MATT SANCHEZ: Yes.

5 (Crosstalk)

6 AUDIENCE MEMBER 3: Were you enshrined in  
7 doing much with UBSD?

8 MATT SANCHEZ: Yes, we have.

9 AUDIENCE MEMBER 3: How is that going?

10 MATT SANCHEZ: I mentioned UBSD in the  
11 session. It's going well sometimes. The beautiful  
12 thing about UBSD is it either works right away or it  
13 doesn't work at all. The other issue with UBSD  
14 techniques is it's very dependent on anything on the  
15 surfaces.

16 AUDIENCE MEMBER 3: Other than just --

17 MATT SANCHEZ: We've been doing them -- it's  
18 best to do them uncoated, so we haven't --

19 AUDIENCE MEMBER 3: No. I mean the ion  
20 sputtered.

21 MATT SANCHEZ: Oh, we haven't got that  
22 sophisticated from that perspective. Most work  
that

1 Brian (ph) did for his PhD work was using filter  
2 preparations and then using geometry is where they were  
3 actually transmitting with the transmission -- it's not  
4 back scatter anymore but it was a transmission mode for  
5 the diffraction pattern generation. We've been trying  
6 to take that into -- what we're doing now, we're  
7 isolating individual particles that we see, like, on  
8 PLM, removing those, putting them on the SEM, getting  
9 the compositional information, then obtaining the  
10 diffraction information at UBSD; and we're probably  
11 about an 85 percent success rate doing it that way.  
12 And we've seen some -- yeah, well, we can talk about  
13 that later, but -- so we're having success there.

14 One of these we're trying to do is actually  
15 tie in the UBSD to the automotive analyses on SEM, but  
16 we're not doubting much -- we're having difficulties at  
17 that. That's far off, I think, before we can merge  
18 those technologies.

19 AUDIENCE MEMBER 4: Have you had success with  
20 all the different asbestos types or --

21 MATT SANCHEZ: No. I would defer to Brian's  
22 PhD and publications. Brian Bannon (ph). Sorry. He's

1 a colleague of mine at RDAG Group. From my  
2 recollection they -- there's issues with the -- there's  
3 a few issues. When you're using the transmission mode,  
4 you have much better spatial resolution; but if the  
5 individual fibers are very, very fine -- I don't  
6 remember where that was, whether it was .1 microns; and  
7 then for somewhere, there was just no signal from them  
8 -- the UBSD technique.

9 It does not work at all with crisapa (ph)  
10 because of that scrolled structure. It just looks at  
11 more of just pretty much IBDS work, but for, you know,  
12 single crystals of amphiboles that are, you know, big  
13 enough for the spatial resolution to work, you can  
14 usually get that from that, assuming there's no  
15 coatings or something on the surfaces.

16 AUDIENCE MEMBER 5: You mentioned  
17 cummingtonite. On the TEM, is that just too complex or  
18 too similar to, you know -- can you still do  
19 diffraction there to identify them?

20 MATT SANCHEZ: Well, absolutely. I think the  
21 -- cummingtonite, for those that don't know, it's a  
22 magnesium amphibole.

1 AUDIENCE MEMBER 5: So --

2 MATT SANCHEZ: And the number of the formula  
3 would be  $Mg_7Si_8O_{22}OH_2$ . So compositionally it would be  
4 the same, or potentially the same, as any anthophyllite  
5 you would encounter. The difference between them is  
6 cummingtonite is part of what's called a monoclinic --  
7 it's part of a monoclinic system. It has different --  
8 it has a different crystal structure. Because of that,  
9 it has different diffraction properties than  
10 anthophyllite. So if you're doing the electron  
11 diffraction correctly and understand the differences in  
12 the space groups, you can make those distinctions  
13 whether it's an orthorhombic amphibole or a monoclinic  
14 amphibole. This is not something that is routinely  
15 done by any laboratory that I know of in the asbestos-  
16 testing world.

17 AUDIENCE MEMBER 5: Pretty straightforward for  
18 anthophyllite. It's orthorhombic. Cummingtonite, its  
19 structures collapse because of the iron in it. It has  
20 more iron than anthophyllite.

21 MATT SANCHEZ: What do you mean? Well, you  
22 still have to collect data and make the measurements



1 and do the indexing; but the real difference there is -  
2 - the important differences are the differences in the  
3 space groups between the monoclinic amphiboles and the  
4 orthorhombic amphiboles.

5 AUDIENCE MEMBER 5: That's what defines them.

6 MATT SANCHEZ: I'm sorry?

7 AUDIENCE MEMBER 5: Yeah. That's what defines  
8 them. That's what differentiates them.

9 MATT SANCHEZ: Yeah. But the issue is  
10 understanding what those are and how those -- and how  
11 those result in the diffraction patterns to make the  
12 appropriate determination. I think that's beyond my  
13 topics here today but --

14 AUDIENCE MEMBER 5: All I'm saying that  
15 there's no cummingtonite asbestos.

16 MATT SANCHEZ: I don't know. I've never seen  
17 it, but cummingtonite is a real -- it's a real  
18 amphibole, so --

19 (Crosstalk)

20 All right. Anything else? All right.

21 (Applause)

22 CATHERINE SHEEHAN: So I think now we can move

1 into the next session, which is questions, discussions  
2 for moderators. So I know we don't have chairs here,  
3 but moderators now can take questions from the  
4 audience.

5 So any questions, discussion points? Yes,  
6 Gary (ph).

7 GREGORY MEEKER: Did I understand in your  
8 group you decided to eliminate any airborne --

9 ANN WYLIE: No.

10 GREGORY MEEKER: -- (inaudible)?

11 ANN WYLIE: In fact, there was discussed -- it  
12 was discussed -- we weren't doing the testing methods  
13 per se, but it was mentioned by several that  
14 aerosolizing the samples might be a useful thing to do.

15 GREGORY MEEKER: Okay.

16 ANN WYLIE: Okay. So it wasn't -- but it  
17 wasn't our -- that wasn't our charge.

18 GREGORY MEEKER: Yeah.

19 AUDIENCE MEMBER 6: So I think we've talked it  
20 out, and there's really an uncertainty, problems. I  
21 think we discussed this at ASTM and definitely at USP.  
22 You have what -- you'll see some of the special, but

1 necessary to keep, certificates. You want a de minimis  
2 sample on some of your reference materials, and that's  
3 important when you're taking a sample for analysis.  
4 Whether you take 10 milligrams or 1 milligram, are they  
5 the same? You have to establish that somehow,  
6 somewhere that when you take on a semblet (ph), if you  
7 don't do duplet, triggerclet (ph), or even for  
8 analysis, in order to rule out and analyze it, we have  
9 to also approach it from that perspective. And you can  
10 say, "Well, it's a fine cosmetic talc or pharmaceutical  
11 talc." Okay. Granted that helps in some situations,  
12 but if you're looking at maybe the courser talcs, you  
13 do have a situation where you have to think about how  
14 you're subsampling and what would really be of the de  
15 minimis sampling before you put it all on diffraction,  
16 PLM, or Tega (ph). So I just think that should be  
17 brought out.

18 CATHERINE SHEEHAN: I'll give you mine just in  
19 case.

20 MARTIN HARPER: Sure. I got a couple of  
21 comments. And one is the availability of proficiency  
22 test samples. I mentioned the HSE's schemes that they

1 occasionally have talc in -- as the material; and I've  
2 mentioned also through ASTM that there's a couple of  
3 initiatives to do some inter laboratory studies, but  
4 they like you to be one-offs, I imagine. Now, it's  
5 perfectly possible to go along to a PT producer in the  
6 US and request a PT sample be added to one of their  
7 programs. In fact, I'm thinking of the American  
8 Industrial Hygiene Association, that bulk asbestos  
9 proficiency testing program. It's -- you know, their  
10 provider is similar to the, you know, NVLAP provider.  
11 I mean, if you wanted a proficiency test sample of talc  
12 contaminated with different materials at different  
13 levels, these can be put together. I mean, obviously  
14 there's a cost involved in the start-up. You know,  
15 there's a cost involved in participation in the program  
16 too, and American Industrial Hygiene Association, pack,  
17 LLC, may be willing to invest money in the creation of  
18 the samples, knowing that they'll get it back from the  
19 participants later, or there might be, you know, a  
20 government agency that would, you know, put a grant  
21 together to enable them to get them. I think it's a  
22 really, really useful thing to do because labs need to

1 know what their capabilities are -- what their true  
2 capabilities are, and you just can't get it by  
3 guesswork.

4 And as it corroborates with that, I also want  
5 to ask that if anyone has, you know, an electron  
6 microscope with an EDS, please, please calibrate it and  
7 calibrate it on the right kind of materials. You know,  
8 reference tremolite, reference actinolite, and please  
9 check the results of those calibrations because, you  
10 know, I've seen results where the actinolite  
11 calibration stat, it was off by 20 percent from 30  
12 percent from the reference composition in the missed  
13 sample. So you know, this is something that I beg the  
14 labs to do.

15 CATHERINE SHEEHAN: Is it on her?

16 GREGORY MEEKER: Could I just -- I'll walk  
17 through quick. He got EIRONG glass -- EIRONG glass,  
18 secondary stick will do for SEM.

19 AUDIENCE MEMBER 7: Martin, to that point,  
20 Session A, we talked about standards as well, on the  
21 calibration standards but also reference standards, of  
22 course; and our biggest obstacle, perhaps, was the fact

1 that -- can we get standards formulated to match a  
2 cosmetic product? We can get Loan Pine. We can go and  
3 -- Money Lab's represented here today and others that  
4 are at least of that status would, you know, have in  
5 their library of standards all these minerals; but I  
6 don't necessarily have something that I could call a  
7 reference material for a base, foundation, cosmetic,  
8 something or another or -- so either can the industry --  
9 so can USP say, "Hey, manufacturer, can you supply the  
10 base formulation of this stuff and then can it either  
11 be spiked or -- we're looking for that bulk matrix  
12 material, not just the mineral fiber itself."

13 CATHERINE SHEEHAN: Happy birthday. No?  
14 Okey-doke.

15 AUDIENCE MEMBER 8: Regardless of the chemical  
16 composition, the various amphiboles and talc and things  
17 like that, Matt, I believe you mentioned in our session  
18 that there was a study that looked at the general  
19 elemental composition of various talcs around the  
20 world. Is that the only study available on that  
21 subject?

22 MATT SANCHEZ: I think it's the most inclusive



1 for sure. I know in the -- what is it? The  
2 International Agency on Research for Cancer? I don't  
3 bet that -- they had -- they had some bold compositions  
4 presented in there from citizens from different top  
5 areas that produced, but with Marian Dosone (ph) at the  
6 Smithsonian Institute, they went to different talc  
7 mining areas; and other gentleman researchers was in  
8 academics and did a lot of work in talc and assembled a  
9 huge collection of talc from all over the world,  
10 different mines; and they made a first passthrough  
11 that, characterizing those things, bulk composition and  
12 some other work using both XRF techniques as well as  
13 EPMA or electro microprobe analysis. And they did some  
14 cluster analyses in trying to look at some correlations  
15 in that paper, but that's the most widespread study I  
16 know, gosh, from everywhere, as many locations as  
17 possible.

18 AUDIENCE MEMBER 9: Roughly, what sensitivity  
19 do those methods have?

20 MATT SANCHEZ: I don't know. They did run  
21 everything by pattern straight fraction as well to  
22 identify the mineral phases, but then they were going

1 through and doing -- it will be sold out for -- the  
2 chemical analyses, I don't recall, but they were doing  
3 a lot of trace element levels down, parts per million,  
4 maybe even parts per billion levels. They were using  
5 the Research Institute over at Washington State  
6 University of Pullman to do a lot of elemental analysis  
7 that way on the bulks.

8 When they got into doing the microprobe work,  
9 it was -- those would have been particle specifics that  
10 they would have identified beforehand; but as far as  
11 the chemical compositions, that's very precise data of  
12 a large suite of both major and minor and then trace  
13 elements.

14 AUDIENCE MEMBER 9: Thank you.

15 CATHERINE SHEEHAN: All right. Were there  
16 questions? No? Going, going, gone. Okay.

17 So I move to close the session if nobody else  
18 has further questions, and we can now go into the  
19 closing remarks and next steps.

20 So these are my closing remarks, not USP's,  
21 but my first closing remark is I wanted to thank  
22 everybody that has come to this meeting today

1 representing us from industry, regulators, and academia  
2 because I think it really did give us that  
3 brainstorming at first. There's a lot of themes,  
4 definitions, and measurement, structure, composition,  
5 shape size. It was a soup of nomenclature, and from  
6 that, there was a lot of questions I felt, and I  
7 thought they were very fundamental questions. Do we  
8 have a definition of what we are testing for? We just  
9 heard many, many times, "Define the mineral. Define  
10 asbestos. Who owns the definition?" We talked about  
11 revising the definition. Perhaps it may need to be  
12 revised. Secondly, in terms of definitions: "What are  
13 we really looking for? What do we want to test for?"  
14 I think these are fundamental as we go into the big  
15 task of developing method and limits.

16 I think the second theme common throughout the  
17 morning session speakers and the sessions was that we  
18 were really looking for a standardized approach that  
19 labs can follow. I think the consensus was that there  
20 is a toolbox out there. No one method will suffice,  
21 but which ones do we used and for what? We also talked  
22 about what is the right reference standard, that that

1 was important as well.

2 So there were my general closing remarks in  
3 terms of what, you know, we discussed both in the  
4 morning and afternoon.

5 So in terms of, I think, next steps -- because  
6 I believe there's a lot of unanswered questions of  
7 those that I mentioned; but to start the ball rolling,  
8 in terms of next steps, I think it's important now that  
9 there's a lot of information shared here, a lot of  
10 critical discussions that will move us on this journey.  
11 But the summary notes definitely, in terms of the  
12 moderators and the speakers, the presentations from  
13 this morning, the summaries from the breakout sessions,  
14 definitely they will need to be posted on the website.  
15 My information here is that has to be finalized by  
16 January 5th. I do not know when they will post, but  
17 January 5th is the deadline for speakers and moderators  
18 to get summary breakout sessions to JIFSAN.

19 Another next steps is to make sure that all  
20 slides that were presented in the morning session and  
21 also as part of the breakouts that they will be  
22 provided on the website.

1 And then third is kind of an open question.  
2 You know, what does the audience think should be a next  
3 step? You know, what have you learned from today that  
4 could help us move to the next step. So I'm going to  
5 leave that as kind of an open question to the audience  
6 in terms of next steps because I think it's important  
7 to hear it from all stakeholders.

8 Any thoughts? I think I see one -- one show  
9 of hands in the back row. Yes.

10 STEVE: About PLM. Just a thought and moving  
11 into (inaudible). Just a thought that be aware that  
12 there are standard development processes currently  
13 taking place concurrently and that my belief is that  
14 everybody that's involved, and certainly all the folks  
15 in this room, ought to provide comment when those --  
16 whenever those standards publish to make sure that we  
17 get the best -- ultimately the best standard. So  
18 that's just a reminder to be on the lookout when things  
19 publish to read them and comment on them.

20 So that -- thank you, Steve (ph).

21 And I don't know if anyone's familiar here  
22 with the USP Standards that are in process, just to

1 follow up on that comment. We have a public comment  
2 period through proposing -- our standards are official,  
3 so if we make any changes to these official standards,  
4 we have to go public and we have to solicit input  
5 comment feedback.

6 Given the number of stakeholders that are  
7 involved and the impact of us revising the USP  
8 Standard, my thoughts are that USP could probably  
9 convene all stakeholders prior to the publication of  
10 this standard so that we could get input before we  
11 actually propose it, because it pretty much -- once it  
12 goes into the PF, the formal PO forum, you have a 90-  
13 day comment period. The expectation is that that will  
14 go before the counsel of experts for approval and  
15 ballot to become official. It's very difficult when it  
16 gets on that track, so I think it's important that we  
17 get some feedback as Jeff (ph) said, that we do this  
18 publicly and we invite all stakeholders in to give us  
19 input on where this revision is going. So --

20 AUDIENCE MEMBER 11: Kind of getting back to  
21 the question about, you know, what to test for and the  
22 definition for asbestos. Based on some of the -- what



1 I've heard here is that there are others compounds that  
2 don't presently fall under the asbestos umbrella that  
3 have similar toxic and carcinogenic effects and should  
4 those compounds be now pitch or clustered underneath  
5 the umbrella of asbestos, or do we need to come up with  
6 a different term than "asbestos" than what we're using  
7 right now? Can it be better descriptive?

8 CATHERINE SHEEHAN: Martin here? Martin?

9 MARTIN RUTSTEIN: This is artificial, and I'm  
10 speaking for myself, but to avoid this dangerous debate  
11 upon what EMP might be out there, I believe that my  
12 colleagues are moving in the direction of using  
13 regulatory asbestos as the group of materials for which  
14 we will have analytical method and that will end that.  
15 If we were to invent -- if we were to develop methods  
16 for these other materials, which may or may not be  
17 hazardous to human health, we would be going into major  
18 uncharted territory, and we collectively didn't think  
19 it would be prudent at this time.

20 CATHERINE SHEEHAN: Thank you, Martin.

21 So any other thoughts? Next steps.

22 AUDIENCE MEMBER 12: Yeah. I was gonna add to

1 what Martin just said that there was -- that we have  
2 been considering that the methodology must develop for  
3 the determination of asbestos as currently defined may  
4 be applicable to other mineral vipers in mineral  
5 counters.

6 MARTIN RUTSTEIN: I left out one thing. I'm  
7 pretty sure in STEM Article 1 we said minerals -- other  
8 minerals that have known hazard.

9 AUDIENCE MEMBER 12: Right.

10 MARTIN RUTSTEIN: I think we included that  
11 one. So that's our ruling. That would be in there if  
12 the evidence is pretty good for it. Like winchite  
13 (inaudible).

14 CATHERINE SHEEHAN: I think that's in the STEM  
15 article, Martin, right?

16 MARTIN RUTSTEIN: In the previous STEM  
17 articles.

18 CATHERINE SHEEHAN: I think -- I would advise  
19 to -- yeah, to -- that goes into the details.

20 MARTIN RUTSTEIN: That's posted. They really  
21 should read it.

22 ANN WYLIE: As was pointed out in our session,

1 the tolerable level is a policy decision, not a  
2 scientific decision. And we need a tolerable level  
3 because an analyst can never prove the absence of  
4 something, and a tolerable level gives an analyst a  
5 target, designs techniques designed to meet that level;  
6 and since that's a policy decision, without that, I  
7 think we really have a problem. So that's an -- FDA  
8 needs to provide that policy decision on what level the  
9 analysts should aim their methodologies.

10 CATHERINE SHEEHAN: Thank you. Okay.

11 MARTIN HARPER: If I might just add --

12 CATHERINE SHEEHAN: Okay.

13 MARTIN HARPER: -- to that. If I may just add  
14 to that that the tolerable level may be different  
15 depending on whether we're talking about, you know,  
16 bulk talc that's feeding into a product line or a final  
17 commercial product. Just a thought kind of.

18 AUDIENCE MEMBER 12: And then, again, we have  
19 to come back to, well, what's detectable and what's  
20 tolerable. If we look at the high court of history,  
21 when we developed standards in the past, the regulatory  
22 agencies have often said, "Anything that's detectable

1 is unacceptable." So if you have a zero-tolerance  
2 policy, then you have to define what your detectability  
3 is, and that becomes your edge point.

4 GREGORY MEEKER: I assume we're talking about  
5 a tolerable level with respect to health?

6 AUDIENCE MEMBER 12: Well, that's why we're  
7 really here.

8 GREGORY MEEKER: Is there a tolerable level  
9 with respect to impact on industry? Should we consider  
10 that also? Because it always seems to fall on the  
11 health side, and I don't know.

12 MARTIN HARPER: That would be more like an  
13 OSHA regulatory process where the socioeconomic impact  
14 has to be dealt with --

15 (Crosstalk)

16 GREGORY MEEKER: No, not worker health. I  
17 mean, the impact on the industry.

18 MARTIN HARPER: Yeah. Well, you know, OSHA's  
19 standards are set taking into account what's achievable  
20 by industry. So for example, the methylene chloride  
21 standard allows a risk above what they would like to  
22 have, simply because the furniture refinishing industry

1 wouldn't exist without methylene chloride and it can't  
2 really be controlled to the level they'd like to  
3 control it. So yeah, I mean, there's definitely  
4 precedent for not setting everything entirely on the  
5 panel.

6 AUDIENCE MEMBER 13: From an FDA perspective,  
7 we want to thank you for all the thoughts and all of  
8 the hard work that went through this morning as well.  
9 And there's a lot of food for thought for all of us,  
10 not just at the FDA but all through regulatory agencies  
11 that are here and a variety of governmental agencies  
12 that are present today as well to go back and think  
13 about what all of our discussions mean for the products  
14 that we all regulate and have some jurisdiction over.  
15 That you.

16 CATHERINE SHEEHAN: Any other comments,  
17 suggestions on next steps? No? Okay.

18 So I believe the meeting is over, but I would  
19 like to give a special thanks to -- I'm gonna call out  
20 everybody because I think everybody did a really great  
21 job. Presenters: Brad, Greg, Martin, Martin, Brooke,  
22 and Ann; and then the afternoon session, the co-

1 moderators: Robyn, Frank, Ann, Art, Brooke, and Matt.

2 Thank you so much.

3 (Applause)

4 And a final thank you to JIFSAN staff, and a

5 special call-out to Veronica -- sorry -- Nora Petty

6 for the assistance in getting the moderators and

7 speakers together and trying to get this altogether.

8 (Applause)

9 Thank you.

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CERTIFICATE OF NOTARY PUBLIC

I, KEVON CONGO, the officer before whom the foregoing proceeding was taken, do hereby certify that the proceedings were recorded by me and thereafter reduced to typewriting under my direction; that said proceedings are a true and accurate record to the best of my knowledge, skills, and ability; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this was taken; and, further, that I am not a relative or employee of any counsel or attorney employed by the parties hereto, nor financially or otherwise interested in the outcome of this action.



KEVON CONGO

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December 9, 2018

DATE

  
CINDY FORRISTER

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